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# The Anti-Deference Pro-Preemption Paradox at the U.S. Supreme Court: The Business Community Weighs In

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THE ANTI-DEFERENCE  
PRO-PREEMPTION PARADOX AT THE  
U.S. SUPREME COURT: THE BUSINESS  
COMMUNITY WEIGHS IN

*Catherine M. Sharkey*<sup>†</sup>

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INTRODUCTION

Much has been written about the alleged pro-business bias of the Roberts Court.<sup>1</sup> According to various commentators, two indicia of the

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1. I would be remiss if the first and foremost citation here were not: BUSINESS AND THE ROBERTS COURT (Jonathan H. Adler ed., 2016), which contains a wealth of references to the relevant literature.

Court's pro-business leanings are, first, its readiness to find state tort law preempted by federal law and, second, its skepticism toward *Auer* deference to federal agencies.<sup>2</sup>

Whether or not these discrete jurisprudential trends support a pro-business agenda, there is an inherent tension between them. It is difficult to reconcile individual Justices'—particularly those identified as part of the “conservative core”—pro-preemption positions and anti-*Auer* positions, and this tension suggests that the oft-advanced pro-business narrative warrants a closer look.

The tension is on clearest display in drug preemption cases, where even the most anti-agency deference Justices readily defer to the Food and Drug Administration (FDA), particularly when the agency's interpretation of its own regulations under *Auer* is at issue.<sup>3</sup> What explains this seeming paradox? One plausible hypothesis is that the conservative core Justices' antipathy toward common law tort regulation runs even deeper than their hostility toward regulation by federal agencies.<sup>4</sup> Indeed, various contemporary arguments for “taming the administrative beast have a distinctly deregulatory thrust”<sup>5</sup>—namely, the object of vilification is regulation itself, whether by agency or common law. But when forced to choose a poison, the Justices side with the agency (FDA) over common law tort.

How does unearthing this seeming paradox affect the conventional narrative of the pro-business Roberts Court? Perhaps the conservative core Justices have indeed followed business interests, which resist regulation of all forms, but when forced to choose would prefer a single federal regulator over multiple forms of state regulation, including common law tort. If this were so, then examination of the business group briefs before the U.S. Supreme Court should reflect the same paradox—namely advocating in favor of more preemption, including preemption by agency action, while simultaneously pushing for reconsideration of *Auer* deference.

This Article examines the extent to which the business community is involved in, and is perhaps even playing a role in perpetuating, this paradox. An examination of recent U.S. Supreme Court cases that im-

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2. See *infra* Part I.A.

3. See, e.g., *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) (ruling by way of the five more-conservative leaning justices, over a dissent joined by the four more-liberal leaning justices, that state tort law was preempted based in part on *Auer* deference to the FDA).

4. See Catherine M. Sharkey, *The Administrative State and the Common Law: Regulatory Substitutes or Complements?* 65 EMORY L.J. 1705, 1733 (2016) (“[I]t would appear that these Justices' hostility toward the common law of torts trumps even their caustic criticism of the ever-inflating administrative state.”).

5. *Id.* at 1708.

plicate questions of *Auer* deference explodes the very notion of a predictable, uniform “business community” position. Depending on the substantive issues at hand, business groups’ amicus briefs can be found on either side of the *Auer* deference question: advocating for it in some instances, and vociferously opposing it in others. In and of itself, this lack of uniformity is not a surprise; the position taken with respect to *Auer* deference tends to be the one that best advances the particular business group’s interests at stake in that particular case.

There are, however, two stalwart outliers: The U.S. Chamber of Commerce and the National Federation of Independent Businesses (the “Chamber” and “NFIB,” respectively). No matter the case, these groups steadfastly resist *Auer* deference. Indeed, the Chamber has been consistent in its opposition to agency deference even when the agency interpretation at issue ostensibly advances its members’ interests.<sup>6</sup>

Many business groups involved in cases where questions of *Auer* deference rear their head tend not to be involved in FDA/federal preemption cases.<sup>7</sup> On the flip side, there are a good number of business groups who intervene only in FDA/federal preemption cases yet have had rare, if any, involvement in cases concerning *Auer* deference outside the preemption context.<sup>8</sup>

But two business groups have members with interests in both lines of cases: the Chamber and the Pharmaceutical Research and Manufacturers of America (“PhRMA”), which represents “the country’s leading biopharmaceutical researchers and biotechnology companies.”<sup>9</sup> It should come as no surprise that these groups consistently advocate for preemption, as do most or all business groups who submit amicus briefs in drug preemption cases. What is of especially great interest here, however, is the degree to which these groups’—particularly the Chamber’s—passionate, consistent advocacy against *Auer* deference is matched by their passionate, consistent advocacy in favor of preemption. As is explored in greater detail below,<sup>10</sup> these groups not only advocate for preemption, but often explicitly ground their arguments on principles of agency deference, even while railing against the notion of deference to agencies outside the preemption context.

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6. See *infra* Part II.A.2.

7. The NFIB, for example, is heavily invested in stemming the tide of regulatory overreach by intervening in cases challenging *Auer* deference, whereas it has not tended to be involved in FDA/federal preemption cases. See *infra* Part II.A.2.

8. The Product Liability Advisory Council (PLAC) provides a paradigmatic example here. See *infra* Part II.B.1.

9. PhRMA, <http://www.phrma.org> [<https://perma.cc/55M8-MEF5>] (last visited Feb. 18, 2017).

10. See *infra* Part II.B.

These groups appear to be taking some steps to harmonize their approaches towards these lines of cases. The Chamber and PhRMA submitted a joint amicus brief in the most recent drug preemption case,<sup>11</sup> in which they advanced preemption arguments, but—strategically—did not ground those arguments on agency deference principles.<sup>12</sup> It remains to be seen whether they will continue to chip away at the paradox in future briefs, and do so by advocating against agency deference across the board.

It also remains to be seen how, if at all, this will affect the Court going forward. Perhaps complicating this question most of all is the totally unknown landscape that lies ahead in the era of President Trump, who has enthusiastically voiced his own anti-regulatory views and has stacked his agency appointments accordingly. Will the business community continue to feel the need to advocate against agency deference when agencies may be mere regulatory shadows of their former selves? Alternatively, might the business community shift strategic gears altogether and adjust its focus away from litigation and towards lobbying Congress and agencies for clearer language, thus obviating the need for courts to defer to any agency interpretation at all? Perhaps this thorny paradox may vanish naturally, and relieve the Court of any (as-yet unacknowledged) burden to parse through it.

## I. THE ROBERTS COURT UNDER SCRUTINY

The conventional narrative of the pro-business Roberts Court has its limits. The Roberts Court has undoubtedly articulated pro-business positions firmly against onerous agency regulation and against many state law claims. However, the Court's attack on agency deference and fear of a proliferating administrative state oddly vanishes when it comes to federal preemption cases involving the FDA. Even the most conservative Justices freely praise the FDA as the optimal regulator of public health and safety.<sup>13</sup>

### *A. Pro-Business Agenda: A Simple Story*

Two story lines have emerged in the pro-business narrative of the Roberts Court. First, the business community has rallied in favor of federal preemption of state tort law claims against manufacturers. Se-

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11. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

12. See Brief of the Chamber of Commerce of the U.S. & Pharm. Research & Mfrs. of Am. as Amici Curiae in Support of Petitioner at 4–11, *Mut. Pharm. Co.*, 133 S. Ct. 2466 (No. 12-142) (outlining the Chamber's and PhRMA's arguments in favor of preemption).

13. See *infra* Part I.B.

cond, the business community has united in its opposition to burdensome federal regulation of business enterprises. And, in distinct lines of jurisprudence, the U.S. Supreme Court has seemed to follow suit.

### 1. Hostility to State Tort Law

Numerous commentators have fit the U.S. Supreme Court's federal preemption jurisprudence into a neat pro-business, anti-consumer narrative.<sup>14</sup> A spotlight has been shone on the recent spate of preemption cases involving prescription medical devices and drugs.

*Riegel v. Medtronic, Inc.*<sup>15</sup> was a watershed moment in federal preemption jurisprudence, as the U.S. Supreme Court signaled that, going forward, it would read "requirements" in a statutory preemption provision to include state common law tort claims.<sup>16</sup> Charles Riegel sued Medtronic under state law for its alleged negligence in designing, manufacturing, and labeling a catheter.<sup>17</sup> The U.S. Supreme Court agreed with Medtronic—and the United States and various business groups as amici<sup>18</sup>—that these state law claims were expressly preempted by the Medical Device Amendments (MDA) to the Food Drug & Cosmetic Act.<sup>19</sup>

Turning from medical devices to prescription drugs, in *Wyeth v. Levine*,<sup>20</sup> Diana Levine brought a state tort law failure-to-warn claim against brand-name drug manufacturer Wyeth for serious injuries that

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14. See, e.g., Erwin Chemerinsky, *The Roberts Court at Age Three*, 54 WAYNE L. REV. 947, 962 (2008) ("[T]he Roberts Court is the most pro-business Court of any since the mid-1930s."); Lee Epstein, William M. Landes & Richard A. Posner, *How Business Fares in the Supreme Court*, 97 MINN. L. REV. 1431, 1472 (2013) ("[T]he Roberts Court is much friendlier to business than either the Burger or Rehnquist Courts, which preceded it, were").
  15. 552 U.S. 312 (2008).
  16. *Id.* at 324 ("Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State's 'requirements' includes its common-law duties.").
  17. *Id.* at 320.
  18. Brief for the United States as Amicus Curiae Supporting Respondent at 27–28, *Riegel*, 552 U.S. 312 (No. 06-179); see, e.g., Brief of the Chamber of Commerce of the U.S. as Amicus Curiae in Support of Respondent at 2, *Riegel*, 552 U.S. 312 (No. 06-179) (arguing that state tort law claims are preempted under prior decisions of the U.S. Supreme Court); Brief of Prod. Liab. Advisory Council, Inc. as Amicus Curiae in Support of Respondent at 19, *Riegel*, 552 U.S. 312 (No. 06-179) (arguing that congressional intent and prior decisions of the U.S. Supreme Court demonstrate that MDA preempts state tort law claims).
  19. *Riegel*, 552 U.S. at 328–29 (citing Brief for the United States as Amicus Curiae Supporting Respondent, *supra* note 18, at 27–28).
  20. 555 U.S. 555 (2009).

occurred after administration of an anti-nausea drug.<sup>21</sup> Wyeth argued that Ms. Levine's claim was preempted because the FDA had approved the warning label on the drug.<sup>22</sup> The U.S. Supreme Court rejected Wyeth's position, notwithstanding support by the United States and several business groups as amici.<sup>23</sup> But the Court then reversed course with respect to preemption of claims against generic drug manufacturers. In *PLIVA, Inc. v. Mensing*,<sup>24</sup> Gladys Mensing and Julie Demahy filed state law failure-to-warn suits against the manufacturer of their generic digestion medication.<sup>25</sup> PLIVA argued that generic drugs are required by federal law to have the exact same labeling as their brand-name equivalents, and thus the plaintiffs claims were preempted because PLIVA, a generic drug manufacturer, could not have unilaterally added any additional warnings onto the drug's label.<sup>26</sup> The U.S. Supreme Court sided with PLIVA<sup>27</sup> (and various business groups as amici, but this time, against the United States's position).<sup>28</sup> And, in *Mutual*

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21. *Id.* at 559–60.

22. *Id.* at 560–61.

23. *Id.* at 580–81. *But see, e.g.*, Brief for the United States as Amicus Curiae Supporting Petitioner at 10, *Wyeth*, 555 U.S. 555 (No. 06-1249) (arguing that the FDCA preempts state tort law claims related to labeling that the FDA has approved); Brief for PhRMA & BIO as Amici Curiae Supporting Petitioner at 5, *Wyeth*, 555 U.S. 555 (No. 06-1249) (arguing that state tort law claims related to labeling undermine the FDA and should be preempted under preemption principles); Brief of the Generic Pharm. Ass'n as Amicus Curiae in Support of Petitioner at 7–13, *Wyeth*, 555 U.S. 555 (No. 06-1249) (arguing that preemption applies in FDA-approved labeling cases).

24. 564 U.S. 604 (2011).

25. *Id.* at 610.

26. *Id.*

27. *Id.* at 624 (“Here, state law imposed a duty on the Manufacturers to take a certain action, and federal law barred them from taking that action. . . . Mensing and Demahy’s tort claims are pre-empted.”).

28. Brief for the United States as Amicus Curiae Supporting Respondents, *PLIVA*, 564 U.S. 604 (Nos. 09-993, 09-1039, 09-1501). The government took the position that “FDA regulations require [brand-name drug manufacturers] and [generic drug manufacturers] alike to act upon new safety information that warrants added or strengthened warnings” so that the agency can “determine whether the labeling for the generic and listed drugs should be revised.” *Id.* at 12 (quoting 57 Fed. Reg. 17,961 (Apr. 28, 1992)). *But see* Brief of Apotex, Inc. as Amicus Curiae in Support of Petitioners at 10–14, *PLIVA*, 564 U.S. 604 (Nos. 09-993, 09-1039, 09-1501) (arguing that both implied and obstacle preemption apply to Mensing’s and Demahy’s claims); Brief of Generic Pharm. Ass’n as Amicus Curiae in Support of Petitioners at 2–3, *PLIVA*, 564 U.S. 604 (Nos. 09-993, 09-1039, 09-1501) (arguing the Congressional policy reasons backing preemption and why they apply in this case).

*Pharmaceutical Co. v. Bartlett*,<sup>29</sup> Karen Bartlett brought a state design defect liability claim against a generic drug manufacturer.<sup>30</sup> Once again, the U.S. Supreme Court held that the state law claim was preempted by federal law regulating the manufacture of generic drugs<sup>31</sup>—a position backed by various business groups as amici,<sup>32</sup> as well as the United States’s position.<sup>33</sup>

The Constitutional Accountability Center (“CAC”)<sup>34</sup> describes *Wyeth*, *PLIVA*, and *Mutual Pharmaceutical* as a “trio of decisions addressing prescription drug safety . . . illustrat[ing] the practical importance and real-world effects of the Roberts Court’s business cases, with Chief Justice Roberts voting with the business community in all three.”<sup>35</sup>

*Wyeth* may seem an odd starting point given that the majority, per Justice Stevens, rejected all of the drug manufacturers’ preemption arguments.<sup>36</sup> But CAC characterizes *Wyeth* as “a powerful example of a case in which Chief Justice Roberts wanted to move the law in a pro-business direction, but members of the conservative wing—in this case, Justices Kennedy and Thomas—balked.”<sup>37</sup>

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29. 133 S. Ct. 2466 (2013).

30. *Id.* at 2470.

31. *Id.* at 2477, 2480 (“Because it is impossible for Mutual and other similarly situated manufacturers to comply with both state and federal law, New Hampshire’s warning-based design-defect cause of action is pre-empted . . .”).

32. *See, e.g.*, Brief of the Chamber of Commerce of the U.S. & Pharm. Research & Mfrs. of Am. as Amici Curiae in Support of Petitioner at 4, *Mut. Pharm.*, 133 S. Ct. 2466 (No. 12-142) (arguing that Mutual’s conflicting federal and state law responsibilities militate in favor of preemption); Brief of the Prod. Liab. Advisory Council, Inc. as Amicus Curiae in Support of Petitioner at 12, *Mut. Pharm.*, 133 S. Ct. 2466 (No. 12-142) (arguing that the FDCA forbade Mutual from complying with state law, and thus preemption applied).

33. *See* Brief for the United States as Amicus Curiae Supporting Petitioner at 14, *Mut. Pharm.*, 133 S. Ct. 2466 (No. 12-142) (arguing that “[*PLIVA*’s] holding that the FDCA preempts state failure to warn claims against generic drug manufacturers controls this case.”).

34. The CAC’s website describes its mission as “a think tank, law firm, and action center dedicated to fulfilling the progressive promise of our Constitution’s text and history.” *About Us*, CONSTITUTIONAL ACCOUNTABILITY CTR., <http://www.theusconstitution.org/about> [<https://perma.cc/DLV3-8ZWL>] (last visited Feb. 16, 2017).

35. TOM DONNELLY, CONSTITUTIONAL ACCOUNTABILITY CTR., ROBERTS AT 10: CHIEF JUSTICE ROBERTS AND BIG BUSINESS 13–14 (2015) <http://theusconstitution.org/sites/default/files/briefs/Roberts-at-10-Business.pdf> [<https://perma.cc/U3WU-T9GS>].

36. *Wyeth v. Levine*, 555 U.S. 555, 579–81 (2008).

37. DONNELLY, *supra* note 35, at 15.



*PLIVA* and *Mutual Pharmaceutical* raise similar state tort claims, but against generic, as opposed to brand-name, prescription drug manufacturers. In both of these cases, the U.S. Supreme Court majority holds that the state law failure to warn and design defect claims, respectively, were preempted by federal law.<sup>38</sup> Once again, fitting the compact narrative, CAC concludes that “[i]n the end, although the legal issues in *PLIVA* and *Mutual Pharmaceutical* may be complicated, the bottom line is easy enough to understand: by siding with the business community, Chief Justice Roberts and his conservative colleagues closed the courthouse doors to certain patients who have been severely injured by generic drugs.”<sup>39</sup>

## 2. Hostility to the Administrative State

A second pro-business narrative highlights efforts by the business community to unite in opposition to aggressive federal regulation. Industry groups commonly decry “executive overreach.”<sup>40</sup> Free-market advocacy groups warn that “[m]illions of Americans are suffering under the weight of burdensome regulation.”<sup>41</sup>

Business group hostility towards federal regulation has translated into questioning or opposing judicial deference to agency decisions. According to the Chamber of Commerce, the “U.S. business community has become increasingly concerned in recent years about the consequences of courts granting too much deference to regulatory decisions made by federal agencies.”<sup>42</sup> The Chamber has therefore voiced its “strong[ ]

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38. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 625 (2011); *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2480 (2013).

39. DONNELLY, *supra* note 35 at 17–18.

40. *The Danger of Deferring to the Bureaucrats*, AM. ENERGY ALL.: ENERGY TOWNHALL (May 17, 2016), <http://americanenergyalliance.org/2016/05/17/10592/> [<https://perma.cc/9DCQ-ZRTW>] (expressing need to “halt[ ] the continuous onslaught of executive overreach in all policy areas, including the energy and environment sector”).

41. Letter from Competitive Enterprise Inst., et al., to Members of the U.S. Congress (June 7, 2016), <https://cei.org/sites/default/files/2016%20Chevron%20SOPRA%20coalition%20letter%20-%20Updated%206222015%20%282%29%20.pdf> [<https://perma.cc/8KZC-JB3Z>]. The Competitive Enterprise Institute argues: “*Auer* provides a perverse incentive for an agency to issue deliberately vague regulations that it can reinterpret as it chooses, avoiding the notice-and-comment requirements of the Administrative Procedure Act for a change in regulation.” *Id.*

42. Letter from R. Bruce Josten, Exec. Vice President of Gov’t Affairs, Chamber of Commerce of the U.S., to Members of the U.S. Congress (Mar. 18, 2016), [https://www.uschamber.com/sites/default/files/documents/files/3.18.16-hill\\_letter\\_to\\_congress\\_supporting\\_h.r.\\_4768\\_and\\_s.\\_2724\\_the\\_separation\\_of\\_powers\\_restoration\\_act.pdf](https://www.uschamber.com/sites/default/files/documents/files/3.18.16-hill_letter_to_congress_supporting_h.r._4768_and_s._2724_the_separation_of_powers_restoration_act.pdf) [<https://perma.cc/FY8J-U7DD>].

support[ ] [for] congressional efforts to restrain excessive judicial deference to agency decision making.”<sup>43</sup> Nor are such concerns limited to groups representing big business. Indeed, small businesses complain that they are “disproportionately harmed by overreaching, costly federal regulations.”<sup>44</sup>

The hostility towards *Auer* deference exhibited by the U.S. Supreme Court’s conservative core is seemingly in line with the thrust of the business community’s position. Sixteen years after writing the *Auer* decision, the late Justice Scalia, in *Decker*, railed against this doctrine of deference to agency interpretations of their own regulations, which he termed “a dangerous permission slip for the arrogation of power.”<sup>45</sup> Elaborating further, Justice Scalia warned: “[w]hen the legislative and executive powers are united in the same person . . . there can be no liberty; because apprehensions may arise, lest the same monarch or senate should enact tyrannical laws, to execute them in a tyrannical manner.”<sup>46</sup>

Before Justice Scalia’s untimely death, there was mounting support amongst the conservative core Justices for revisiting *Auer*. In *Perez v. Mortgage Bankers Ass’n*,<sup>47</sup> Justice Alito empathized with the D.C. Circuit’s creation of the *Paralyzed Veterans* doctrine, which required an agency seeking to amend a substantive interpretive rule to comply with notice-and-comment rulemaking procedures, suggesting it was:

prompted by an understandable concern about the aggrandizement of the power of administrative agencies as a result of the combined effect of (1) the effective delegation to agencies by Congress of huge swaths of lawmaking authority, (2) the exploitation

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43. *Id.*

44. Karen Kerrigan, *Letter to U.S. House: “Separation of Powers Restoration Act,”* SBE COUNCIL (June 27, 2016, 1:48 PM), <http://sbecouncil.org/2016/06/27/letter-to-u-s-house-separation-of-powers-restoration-act/> [<https://perma.cc/EM63-B67Z>]; see Letter from TechFreedom, et al., to Members of the U.S. Congress (July 11, 2016), <http://docs.techfreedom.org/SOPRALetter.pdf> [<https://perma.cc/ALT9-F647>] (“*Chevron* means Internet regulation will now be a game of political ping-pong—with the courts resigned to sitting on the sidelines, watching the ball bounce back and forth[, creating] ongoing uncertainty [that] is particularly damaging to small businesses, who often lack the resources needed to comply with shifting regulatory burdens and litigate against unfavorable regulatory changes.”). TechFreedom’s letter was cited by a sponsor of the bill during the House debate. 162 CONG. REC. H4615, H4617 (daily ed. July 11, 2016).

45. *Decker v. Nw. Env’tl. Def. Ctr.*, 133 S. Ct. 1326, 1341 (2013) (Scalia, J., concurring in part and dissenting in part).

46. *Id.* (quoting BARON DE MONTESQUIEU, *THE SPIRIT OF LAWS* 151–52 (Thomas Nugent trans., O. Piest ed. 1949) (1748)).

47. 135 S. Ct. 1199 (2015).

by agencies of the uncertain boundary between legislative and interpretive rules, and (3) this Court's cases holding that courts must ordinarily defer to an agency's interpretation of its own ambiguous regulations.<sup>48</sup>

Justice Thomas characterized *Auer* as “a transfer of the judge's exercise of interpretive judgment to the agency.”<sup>49</sup> Justice Scalia, perhaps emboldened by support from his conservative brethren, made a pitch for altogether abandoning the doctrine: “[T]here are weighty reasons to deny a lawgiver the power to write ambiguous laws and then be the judge of what the ambiguity means. I would therefore restore the balance originally struck by the APA with respect to any agency's interpretation of its own regulations . . . by abandoning *Auer* . . . .”<sup>50</sup>

*B. Deference to Federal Agencies: A Paradox Emerges*

Thus far, the pro-business Roberts Court story line seems fairly straightforward—namely the Court has, by and large, acceded to the business community's interests in resisting common law tort claims against manufacturers and stemming the tide of administrative regulations. But obscured from this conventional narrative is consideration of a paradox that emerges when the Court's pro-preemption and anti-deference lines of jurisprudence seem to collide. Namely, the conservative core Justices' attack on agency deference and wider distaste for and distrust of the administrative state is suspended in federal drug preemption cases, in which they give enormous deference to the FDA. No doubt this reflects the Justices' hostility toward the common law of torts as a regulator. Indeed, the Justices repeatedly emphasize the institutional advantages of a regulatory scheme enforced by such an expert agency as the FDA.<sup>51</sup> They herald the FDA's broad perspective on larger public health goals over myopic juries that focus only on the injured plaintiff before them when deciding state tort law claims.<sup>52</sup> The Justices'

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48. *Id.* at 1210 (Alito, J., concurring in part and concurring in the judgment).

49. *Id.* at 1219 (Thomas, J., concurring in the judgment).

50. *Id.* at 1212–13 (Scalia, J., concurring in the judgment) (citations omitted). Justice Scalia reiterated the concerns he had outlined previously in *Decker*: “Because the agency (not Congress) drafts the substantive rules that are the object of those interpretations, giving them deference allows the agency to control the extent of its notice-and-comment-free domain. To expand this domain, the agency need only write substantive rules more broadly and vaguely, leaving plenty of gaps to be filled in later, using interpretive rules unchecked by notice and comment.” *Id.* at 1212.

51. *See, e.g.,* *Wyeth v. Levine*, 555 U.S. 555, 604–06 (2009) (Alito, J., dissenting) (framing the preemption question as partly a choice between the agency's expertise and the expertise of the parties' witnesses at trial).

52. *See, e.g., id.* at 626 (“[J]uries are ill equipped to perform the FDA's cost-benefit-balancing function. . . . [J]uries tend to focus on the risk of a particular

reliance on *Auer* deference in this preemption line of jurisprudence stands in sharp contrast to the emerging line of cases calling for *Auer*'s demise.

Consider *Wyeth v. Levine*, the case in which the majority rejected preemption of state law tort claims against a brand-name manufacturer.<sup>53</sup> In a vehement dissent, Justice Alito, joined by Chief Justice Roberts and Justice Scalia, criticized the majority for “turning a common-law tort suit into a ‘frontal assault’ on the FDA’s regulatory regime for drug labeling,”<sup>54</sup> embracing the “frontal assault” terminology from the United States’s amicus brief in support of *Wyeth*.<sup>55</sup> The dissenting Justices showed no hesitation in giving the FDA far-reaching deference—in this case, relying on the agency’s view as put forth in a preamble to a regulation.<sup>56</sup> This expansive view of deference to the underlying federal regulator is not easily reconciled with the conservative core’s attack on the administrative state.<sup>57</sup>

The starkest example to date is the puzzling persistence of *Auer* deference as a pillar of preemption in the generic drug context. In *PLIVA v. Mensing*, in a majority opinion by Justice Thomas, the Court defers to the FDA: “[t]he FDA . . . tells us that it interprets its regulations to require that the warning labels of a brand-name drug and its generic copy must always be the same—thus generic drug manufacturers have an ongoing federal duty of ‘sameness.’”<sup>58</sup> In so doing, the

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product’s design or warning label that arguably contributed to a particular plaintiff’s injury, not on the overall benefits of that design or label . . . . In contrast, the FDA has the benefit of the long view.”) (citations omitted).

53. *Id.* at 579–81 (majority opinion).

54. *Id.* at 606 (Alito, J., dissenting).

55. Brief for the United States as Amicus Curiae Supporting Petitioner, *supra* note 23, at 21.

56. See *Wyeth*, 555 U.S. at 622–23 (Alito, J., dissenting) (“[P]re-emption is arguably more appropriate here than in *Geier* because the FDA (unlike the DOT) declared its pre-emptive intent in the Federal Register.”) (citing 71 Fed. Reg. 3933–3936); see also *id.* at 623 (citing Justice Breyer’s concurring opinion in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 506 (1996) for the proposition that the preamble to the regulation should carry greater weight because the FDA includes its understanding of state and federal requirements in the preamble).

57. It is striking that Justice Thomas (writing a separate concurrence in *Wyeth*) stands alone in eschewing any reliance on agency comments, regulatory history, and agency litigating positions in implied preemption analysis. *Id.* at 600–01 (Thomas, J., concurring) (“[N]o agency . . . can preempt a State’s judgment by merely musing about goals or intentions not found within or authorized by the statutory text.”). For further elaboration, see Catherine M. Sharkey, *Against Freewheeling, Extratextual Obstacle Preemption: Is Justice Clarence Thomas the Lone Principled Federalist?*, 5 N.Y.U. J.L. & LIBERTY 63 (2010).

58. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011) (citing Brief for the United States as Amicus Curiae Supporting Respondents, *supra* note 28, at 16).

Justices invoke *Auer* deference repeatedly (and with no hesitation): “The FDA’s views are ‘controlling unless plainly erroneous or inconsistent with the regulation[s]’ or there is any other reason to doubt that they reflect the FDA’s fair and considered judgment.”<sup>59</sup> As a result, the Court “defer[red] to the FDA’s interpretation of its CBE [‘changes being effected’ drug labeling regulation] and generic labeling regulations.”<sup>60</sup>

## II. BUSINESS COMMUNITY AGENDA

A closer look at the recent cases implicating *Auer* deference undercuts the very notion of a “business community” position on the issue. Depending on the matter at hand, the particular business group(s) whose members are affected, and the relevant agency’s interpretive position on the regulation at issue, business groups might just as likely advocate in favor of deference as against it. The two outliers are the Chamber of Commerce and the National Federation of Independent Businesses, who consistently oppose *Auer* deference.

### A. Agency Deference

Business groups on the whole have deployed *Auer* deference arguments strategically, invoking *Auer* when the federal regulator’s position aligns with the business interest at stake while attempting to limit or even disparage the doctrine when the federal regulator is at odds with the relevant business interest. It would thus seem that there is not a consistent or monolithic pro-business hostility to *Auer* deference.

Against this backdrop, however, the Chamber has consistently opposed *Auer* deference.<sup>61</sup> And the NFIB—representing 350,000 member businesses as the nation’s leading small business association—has identified *Auer* deference as the prime target of its attack.<sup>62</sup>

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59. *Id.* at 613 (quoting *Auer v. Robbins*, 519 U.S. 452, 461 (1997)).

60. *Id.* at 614. Note too that, in *Mutual Pharmaceutical*, the majority per Justice Alito relied on federal drug regulations “as interpreted by the FDA” in deeming state law preempted. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2476 (2013).

61. *See infra* Part II.A.2.

62. *See Five Things NFIB Is Doing to Cabin Agency Discretion*, NAT’L FED’N OF INDEP. BUS. (Nov. 8, 2016), <http://www.nfib.com/content/legal-blog/legal/five-things-nfib-is-doing-to-cabin-agency-discretion-75891/> [<https://perma.cc/8M2S-24SZ>] (“[I]n *United States v. Texas*, and in *Flytenow v. FAA*, we argued that it was time for the Court [to] overturn *Auer v. Robbins* . . . .”); Kerrigan, *supra* note 44 (“[Making sure that] ‘agencies’ interpretations of law would no longer receive deference [is] exactly the remedy small businesses need to get a fair shake in courts.”). The letter praises the introduction of the “Separation of Powers Restoration Act” legislation as “a good start to rein in a bureaucracy that is stifling growth, innovation, competitiveness, and new business startups.” *Id.* The *Chevron* doctrine is another key

## 1. Vacillating Positions on *Auer* Deference

### *a. Reliance on Auer Deference*

Several high-profile U.S. Supreme Court cases illustrate where groups representing business and industry interests urged the Court to ratify, and even expand, *Auer* deference principles.

The American Bankers Association—representing small, regional, and large banks throughout the United States<sup>63</sup>—has made its endorsement of *Auer* deference plain, at least in cases in which deference to the position espoused by the Federal Reserve Board supports its own position.

In *Chase Bank USA, N.A. v. McCoy*,<sup>64</sup> a plaintiff class of credit card holders sued defendant Chase Bank, alleging that it had violated the Truth in Lending Act (TILA) by increasing interest rates retroactively after credit accounts were closed.<sup>65</sup> The Ninth Circuit Court of Appeals ruled in favor of the credit card holders, notwithstanding the fact that the Federal Reserve Board interpreted its own “Regulation Z” of TILA as not requiring a creditor to provide cardholders with a change-of-term notice.<sup>66</sup> On appeal to the U.S. Supreme Court, the Federal Reserve Board also filed an amicus brief in support of Chase.<sup>67</sup>

The American Bankers Association sharply criticized the Ninth Circuit for failing to defer to the Federal Reserve Board’s interpretation of its own regulation.<sup>68</sup> “In terms of policy,” the American Bankers

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target; this doctrine of judicial deference to agency statutory interpretation is described as “a dangerous judicial abdication that has fueled overregulation and the growth of the administrative [state] for decades.” *Id.*

63. According to the American Bankers Association website: “The American Bankers Association is the united voice of America’s hometown bankers[—]small, regional and large banks that together employ more than 2 million women and men, hold nearly \$17 trillion in assets, safeguard \$12.8 trillion in deposits and extend more than \$9 trillion in loans.” *About the American Bankers Association*, AM. BANKERS ASS’N, <http://www.aba.com/About/Pages/default.aspx> [<https://perma.cc/LG2F-T7LG>] (last visited Feb. 19, 2017).
64. 562 U.S. 195 (2011).
65. *Id.* at 201–02.
66. *Id.* The U.S. Supreme Court reversed with a unanimous decision that applied *Auer* deference to the Board’s interpretation that Regulation Z does not require a creditor to provide cardholders with a change-of-term notice. *Id.* at 208 (“Under *Auer* . . . we defer to an agency’s interpretation of its own regulation, advanced in a legal brief, unless that interpretation is plainly erroneous or inconsistent with the regulation.”) (citations omitted).
67. Brief for the United States as Amicus Curiae, *Chase Bank*, 562 U.S. 195 (No. 09-329).
68. Brief of the Am. Bankers Ass’n as Amicus Curiae in support of Petitioner at 4, *Chase Bank*, 562 U.S. 195 (No. 09-329) (criticizing the Ninth Circuit for failing to defer to the “interpretation of Regulation Z by the Board, which has

Association argued, “the Ninth Circuit’s failure to defer to interpretive statements by the Board undermines the banking industry’s ability to rely on the Board’s expertise in a ‘highly technical’ area of the law where ‘creditors need sure guidance.’”<sup>69</sup> The American Bankers Association invoked the “long line of cases beginning with [*Seminole Rock*, the precursor to the *Auer* doctrine], [in which] the Court has held that where an agency interprets its own regulations, ‘the ultimate criterion is the administrative interpretation, which becomes of controlling weight unless it is plainly erroneous or inconsistent with the regulation.’”<sup>70</sup> Quoting *Auer*, the American Bankers Association insisted that “deference to an agency’s interpretation of its own regulations is warranted so long as the interpretation ‘reflect[s] the agency’s fair and considered judgment on the matter in question.’”<sup>71</sup>

The American Bankers Association was equally emphatic that deference was due even to informally issued agency interpretations.<sup>72</sup> It took the opportunity to remind the U.S. Supreme Court that the Court had “been willing to defer to agency interpretations of regulations where they appear in a legal brief, or in an ‘Advisory Memorandum’ issued only to internal agency personnel and which the agency appeared to have written in response to pending litigation.”<sup>73</sup> And it lamented that the Ninth Circuit’s decision “calls into question the continued ability of financial institutions to reasonably—and safely—rely on anything

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recently made its position crystal clear via *amicus* filings in this and other proceedings”).

69. *Id.* at 5. (quoting *Ford Motor Credit Co. v. Milhollin*, 444 U.S. 555, 566 (1980)). The American Bankers Association elaborated: “The [Ninth Circuit] panel failed to account for the value to the industry of being allowed to rely on official agency statements or interpretations (albeit less formal than a final regulation) for guidance with respect to TILA or other regulatory issues.” *Id.*
70. *Id.* at 17. (quoting *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945)).
71. *Id.* at 18 (omission in original) (quoting *Auer v. Robbins*, 519 U.S. 452, 462 (1997)); see also *id.* at 19–20. (“The Board’s plain and repeated statements—whether they are offered in an *amicus* brief submitted by the agency or contained in regulatory documents such as the preamble to a proposed rule that is published in the Federal Register—plainly ‘reflect the agency’s fair and considered judgment on the matter in question.’” (quoting *Auer*, 519 U.S. at 462)).
72. *Id.* at 17–18. Note the sharp contrast between the American Bankers Association’s position here in favor of deference to informally issued interpretations and the vehement opposition to such deference voiced by business groups in other cases. See *infra* Part II.A.1.b.
73. Brief of the Am. Bankers Ass’n as Amicus Curiae in Support of Petitioner, *supra* note 68, at 18; see also *id.* at 19 (“Courts regularly defer to agency interpretations of their own regulations that are embodied in considerably less formal statements than those at issue in the present litigation.”).

other than formal statements or guidance issued by the Board via notice and comment rulemaking.”<sup>74</sup>

In *Talk America, Inc. v. Michigan Bell Telephone Co.*,<sup>75</sup> Sprint Nextel and Comptel, two telecommunications corporations that benefited from a Federal Communication Commission interpretation, likewise argued for *Auer* deference.<sup>76</sup> In that case, Michigan Bell, a subsidiary of AT&T, challenged the Michigan Public Service Commission’s interpretation of the Telecommunications Act as requiring incumbent local exchange carriers—like Michigan Bell—to give access to their equipment and services to competitive local exchange carriers at cost.<sup>77</sup> The Sixth Circuit Court of Appeals held that “*Auer* deference [is] unavailing . . . because the [Federal Communication Commission’s] proffered interpretation is so plainly erroneous or inconsistent with the regulation . . . that we can only conclude that the FCC has attempted to create a new *de facto* regulation under the guise of interpreting the regulation.”<sup>78</sup>

Sprint Nextel and Comptel were competitive local exchange carriers advantaged by the FCC’s interpretation. In seeking *Auer* deference, Sprint Nextel stated plainly that “[a]n agency’s interpretation of its own regulations is entitled to deference as long as it is not ‘plainly erroneous or inconsistent with the regulation[s]’ . . . and such deference is amply warranted here.”<sup>79</sup> It argued that such deference was especially

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74. *Id.* at 19.

75. 564 U.S. 50 (2011).

76. Brief for Sprint Nextel Corp. as Amicus Curiae Supporting Petitioners at 19, *Talk Am., Inc.*, 564 U.S. 50 (Nos. 10-313, 10-329); Brief for Amicus Curiae Comptel in Support of Petitioners at 2–3, *Talk Am., Inc.*, 564 U.S. 50 (Nos. 10-313, 10-329).

77. *Talk Am., Inc.*, 564 U.S. at 55.

78. *Mich. Bell Tel. Co. v. Covad Commc’ns Co.*, 597 F.3d 370, 375 n.6 (6th Cir. 2010). The U.S. Supreme Court reversed. The majority looked to the FCC’s interpretation of its regulations to resolve the ambiguities in the statutory scheme, and deferred to that interpretation after finding it “reasonable.” *Talk Am., Inc.*, 564 U.S. at 59–67. “[W]e defer to an agency’s interpretation of its regulations, even in a legal brief, unless the interpretation is ‘plainly erroneous or inconsistent with the regulation[s]’ or there is any other ‘reason to suspect that the interpretation does not reflect the agency’s fair and considered judgment on the matter in question.’” *Id.* at 59 (quoting *Auer v. Robbins*, 519 U.S. 452, 461–62 (1997)).

79. Brief for Sprint Nextel Corp. as Amicus Curiae Supporting Petitioners, *supra* note 76, at 19 (quoting *Auer*, 519 U.S. at 461). Sprint Nextel elaborates: “[T]he most that can be said about the regulations and orders at issue is that they ‘do not give a definitive answer’ to the question presented. . . . [Accordingly,] it certainly cannot be said that the FCC’s regulations and orders unambiguously compel a contrary interpretation . . . [so] [d]eference to the FCC’s interpretation is therefore appropriate.” *Id.* at 19–20. Moreover, Sprint Nextel argued that there “is no other valid basis for refusing to defer to the FCC’s



warranted given “the notorious complexity both of the underlying technology and of the applicable legal regime,” making this “the archetypal case in which deference to the views of an expert agency is appropriate.”<sup>80</sup> Comptel likewise complained that the Sixth Circuit improperly failed to defer to “the FCC’s rules implementing the statute and the agency’s interpretation of those rules.”<sup>81</sup> It chastised the Sixth Circuit for “substituting its own judgment for that of the expert agency not only with respect to the manner in which telephone networks are designed and operate but also with respect to the meaning of the expert agency’s own regulations” notwithstanding the fact that “Congress has delegated to the FCC the authority to resolve any ambiguities” and “[t]he FCC’s interpretation of the term is therefore entitled to considerable weight.”<sup>82</sup>

In *Coeur Alaska, Inc. v. Southeast Alaska Conservation Council*,<sup>83</sup> the Southeast Alaska Conservation Council sued the U.S. Army Corps of Engineers for granting a permit to Coeur Alaska to discharge wastewater from its mining operations into an Alaskan lake.<sup>84</sup> The Ninth Circuit Court of Appeals agreed with the Conservation Council that the Army Corps did not have authority under the Clean Water Act to issue such a permit.<sup>85</sup> Before the U.S. Supreme Court, a number of

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interpretation” because this is neither a situation in which the regulation falls within the “parrotting” exception to *Auer* deference articulated in *Gonzales v. Oregon*, 546 U.S. 243, 257 (2006), nor one in which “the agency’s position is simply ‘a “*post hoc*” rationalization’ advanced . . . to defend past agency action against attack.” *Id.* at 20 (omissions in original) (quoting *Auer*, 519 U.S. at 462).

80. Brief for Sprint Nextel Corp. as Amicus Curiae Supporting Petitioners, *supra* note 76, at 21.
81. Brief for Comptel as Amicus Curiae in Support of Petitioners, *supra* note 76, at 3; *see also id.* at 17–18 (“The Sixth Circuit found the FCC’s interpretation . . . to be ‘so plainly erroneous or inconsistent with the regulation’ as to warrant no deference. But the FCC’s interpretation is neither erroneous nor inconsistent with any regulation.” (citation omitted)). Comptel urged the U.S. Supreme Court to grant *Chevron* deference to the FCC’s rules implementing the Telecommunications Act. *Id.* at 18–19.
82. *Id.* at 9–11.
83. 557 U.S. 261 (2009).
84. *Id.* at 266.
85. *Coeur Alaska, Inc. v. U.S. Army Corps of Eng’rs*, 486 F.3d 638, 655 (9th Cir. 2007) (ruling that the Army Corps improperly interpreted the Clean Water Act when granting permits). Reversing the Ninth Circuit, the U.S. Supreme Court accorded *Auer* deference to an internal memorandum of the EPA. *Coeur Alaska*, 557 U.S. at 283–84 (noting that the memorandum “is entitled to a measure of deference because it interprets the agencies’ own regulatory scheme” (citing *Auer v. Robbins*, 519 U.S. 452, 461 (1997))); *see also id.* at 278 (“accept[ing] it as correct” (citing *Auer*, 519 U.S. at 461)); *id.* at

business groups filed amicus briefs in support of Coeur Alaska and relied explicitly on agency deference doctrines. The Resource Development Council for Alaska<sup>86</sup> explicitly invoked *Seminole Rock* to criticize the Ninth's Circuit's "failure to accord . . . deference in this case," which it argued was contrary to the U.S. Supreme Court's "long-established principle of administrative law," thus "set[ting] a dangerous precedent against the extraordinary deference that must be afforded to an agency's interpretation of its own regulations."<sup>87</sup> The National Association of Home Builders agreed that the "case boils down to agency deference,"<sup>88</sup> and asserted that "[d]eference is due to the expert decisions by the [Army] Corps (and EPA)."<sup>89</sup> In similar fashion, the Council of Alaska Producers urged the U.S. Supreme Court to "reverse the Ninth Circuit's ruling, and defer to the expertise of the Corps and EPA, which

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284–86 (detailing the five factors that led the Court to conclude that "the Memorandum presents a reasonable interpretation of the regulatory regime").

86. The Resource Development Council for Alaska is a "trade organization comprised of businesses and individuals from all resource sectors." Brief of the Res. Dev. Council for Alaska, Inc. as Amicus Curiae in Support of Petitioners at 1, *Coeur Alaska*, 557 U.S. 261 (Nos. 07-984, 07-990).
87. *Id.* at 29 (citing *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945)). The Council argued further that "the Ninth Circuit's holding . . . runs counter to the plain language of the Act, and overturns the EPA's and the Corps' carefully considered permitting program for the regulation of mine tailings." *Id.*
88. Supplemental Brief of Amicus Curiae Nat'l Ass'n of Home Builders Supporting Petitioners at 3, *Coeur Alaska*, 557 U.S. 261 (Nos. 07-984, 07-990). The National Association of Home Builders—along with the Council of Alaska Producers and the National Mining Association—exhorted the Court to accord *Chevron* deference to the Army Corps' interpretation of the Clean Water Act. See Brief of the Council of Alaska Producers as Amicus Curiae in Support of Petitioners at 3, *Coeur Alaska*, 557 U.S. 261 (Nos. 07-984, 07-990) (arguing that the Army Corps appropriately balanced the environmental and economic implications of the Clean Water Act); see also Brief Amici Curiae of the Nat'l Mining Ass'n, et al. in Support of Petitioners at 14, *Coeur Alaska*, 557 U.S. 261 (Nos. 07-984, 07-990) (arguing the conflict should be resolved by expert agencies); Supplemental Brief of Amicus Curiae Nat'l Ass'n of Home Builders Supporting Petitioners, *supra*, at 3 ("[T]he question for the court is whether the agency's answer is based on a permissible construction of the statute." (quoting *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984))).
89. Supplemental Brief of Amicus Curiae Nat'l Ass'n of Home Builders Supporting Petitioners, *supra* note 88, at 3. Here, the National Association of Home Builders relied on *Chevron* (as opposed to *Auer*) deference, but the thrust of its support for deference to the agency based upon its expertise is clear. See Brief of Amicus Curiae Nat'l Ass'n of Home Builders Supporting Petitioners at 10, *Coeur Alaska*, 557 U.S. 261 (Nos. 07-984, 07-990) ("Whether a discharge of sediment is more likely to move downstream . . . 'is a classic example of a factual dispute the resolution of which implicates substantial agency expertise.'" (citing *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 376 (1989))).

have developed a regulatory regime that addresses the relevant environmental concerns raised in this case.”<sup>90</sup> And the National Mining Association concurred, stating that “the Court should defer to the expert agencies’ resolution of the issue—a resolution that is clear, that is of long standing, and that reasonably balances [Congress’s] concerns . . . .”<sup>91</sup>

*b. Rejection of Auer Deference*

Business interest groups just as readily weigh in against deference to the underlying regulating agency’s interpretation where the interpretation at issue conflicts with their own agenda. Indeed, in the *Auer* case itself, the business community rallied behind the no-deference position. The Chamber of Commerce submitted an amicus brief in support of the police commissioners that argued that petitioners were exempt from overtime pay requirements under the Fair Labor Standards Act (FLSA).<sup>92</sup> The Chamber specifically argued that the Department of Labor’s interpretation of its regulations to the contrary “is entitled to little or no deference.”<sup>93</sup> The Chamber focused attention on the inconsistencies in the position taken by the Department of Labor over time and argued that, “[w]hile an agency’s interpretation of its own regulations is generally to be followed unless ‘it is plainly erroneous or inconsistent with the regulation,’ substantially less deference is due when an agency has put forth inconsistent interpretations, as the Department of Labor has done [here].”<sup>94</sup> The Labor Policy Association—“an organization of

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90. Brief of the Council of Alaska Producers as Amicus Curiae in Support of Petitioners, *supra* note 88, at 3 (“The facts of this case demonstrate the need for deference to a reasonable interpretation of statutory terms—such as that provided by the Corps and EPA in this case.”).

91. Brief Amici Curiae of the Nat’l Mining Ass’n, et al. in Support of Petitioners, *supra* note 88, at 14–15. As an initial matter, the National Mining Association argued that the “Clean Water Act’s plain language is dispositive” in favor of Coeur Alaska, but that if the Court found the statute ambiguous, “the agencies entrusted to fulfill Congress’s commands would be left to reconcile conflicting statutory mandates.” *Id.* at 14. Indeed, according to the National Mining Association, the conflicting statutory mandates were “precisely the sort of statutory ambiguity that may be resolved by expert agencies—and whose resolution thereby is entitled to judicial deference.” *Id.* at 15. Here, too, the National Mining Association invoked *Chevron* (as opposed to *Auer*) deference: “this principle—that an agency’s resolution of warring statutory mandates is analyzed under *Chevron*—is not open to serious dispute.” *Id.* at 16.

92. Brief Amici Curiae of the Chamber of Commerce of the U.S. & the Fair Labor Standards Act Reform Coal. in Support of Respondents, *Auer v. Robbins*, 519 U.S. 452 (1997) (No. 95-897), 1996 WL 585673 at \*3.

93. *Id.* at \*16 n.7.

94. *Id.* (quoting *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945) and citing *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 510–12, 514–16 (1994)). The Chamber argued, in the alternative, that “[i]n any event, the

the senior human resources officers of nearly 240 of this nation's largest private sector employers"<sup>95</sup>—also filed an amicus brief in support of the police commissioners, and likewise argued against deference to the agency.<sup>96</sup> The Labor Policy Association contended that “[l]egislative, or substantive, regulations are ‘issued pursuant to statutory authority and . . . have the force and effect of law,’” but “by way of contrast, a court is not required to give effect to an interpretive regulation. Varying degrees of deference are accorded to administrative interpretations based on such factors as the timing and consistency of the agency’s position.”<sup>97</sup> Thus, according to the Labor Policy Association, “although DOL’s interpretations are entitled to some weight,” they are “not ‘entitled to the same deference as norms that derive from the exercise of . . . delegated lawmaking power.’”<sup>98</sup>

The overtime provisions of the FLSA were once again before the U.S. Supreme Court in *Christopher v. SmithKline Beecham Corp.*<sup>99</sup> In that case, pharmaceutical sales representatives, supported by the Secretary of Labor as amicus, denied that they fell within the “outside salesmen” exception to the FLSA overtime requirements.<sup>100</sup> The Ninth Circuit had ruled against them.<sup>101</sup>

Various business groups filed amicus briefs in support of SmithKline Beecham and against the sales representatives; all attempted to limit the scope of *Auer*. The Chamber of Commerce argued “where, as here, an agency’s regulations at most clarify only that certain situations are *included* in the coverage of statutory provision, but offer no guidance as to the outer limits of the statute, an agency’s litigation position regarding those limits is not entitled to deference under *Auer*” given that “the agency has not engaged with the public or brought its expertise to bear on the relevant question of the contours of the statute.”<sup>102</sup>

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Department’s latest interpretation is plainly erroneous and inconsistent with the regulations.” *Id.*

95. Brief of the Labor Policy Ass’n as Amicus Curiae in Support of Respondents, *Auer*, 519 U.S. 452 (1997) (No. 95-897), 1996 WL 585671 at \*1.
96. *See id.* at \*7–16 (arguing that the Department of Labor’s salary basis test is an outdated interpretation that is not entitled to deference).
97. *Id.* at \*7 (omission in original) (quoting *Batterton v. Francis*, 432 U.S. 416, 425 n.9 (1977)).
98. *Id.* at \*8 (quoting *Martin v. Occupational Safety & Health Review Comm’n*, 499 U.S. 144, 157 (1991)).
99. 132 S. Ct. 2156 (2012).
100. *Id.* at 2159.
101. *Christopher v. SmithKline Beecham Corp.*, 635 F.3d 383, 401 (9th Cir. 2011).
102. Brief of Chamber of Commerce of the U.S. as Amicus Curiae in Support of Respondent at 5, *SmithKline Beecham*, 132 S. Ct. 2156 (No. 11-204). The Chamber argued that the “parroting exception” to *Auer* deference applied to

The Washington Legal Foundation (“WLF”) echoed this theme, arguing that “the law does not permit an agency to regulate by amicus brief,” because “[w]hatever else *Auer* . . . may be said to require, it has never been understood to ‘permit the agency, under the guise of interpreting a regulation, to create *de facto* a new regulation.’”<sup>103</sup> WLF complained that the Department of Labor’s “novel interpretation of the FLSA’s outside sales exemption . . . abruptly contradicts the Department’s own regulatory and interpretative guidance to the contrary for over seventy years.”<sup>104</sup> This “abrupt and unexpected departure,” according to WLF, indicated that the interpretation “did not reflect the agency’s ‘fair and considered judgment’ on the matter in question,” and instead suggested that the agency was “engaging in an after-the-fact

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DOL’s regulation implementing the FLSA. *Id.* at 19 (“An agency does not acquire special authority to interpret its own words when, instead of using its expertise and experience to formulate a regulation, it has elected merely to paraphrase the statutory language.”) (quoting *Gonzales v. Oregon*, 546 U.S. 243, 257 (2006)).

103. Brief of Wash. Legal Found. et al. as Amici Curiae in Support of Respondent at 10, *SmithKline Beecham*, 132 S. Ct. 2156 (No. 11-204) (quoting *Christensen v. Harris Cty.*, 529 U.S. 576, 588 (2000)). WLF has not been steadfast in its resistance to *Auer* deference. Consider, for example, its amicus intervention in *Allegheny Teledyne Inc. v. United States*, 316 F.3d 1366 (Fed. Cir. 2003), *cert. denied sub nom.*, *Gen. Motors Corp. v. United States*, 540 U.S. 1068 (2003). WLF argued that the Federal Circuit improperly “dismissed the views of the promulgating and implementing agencies,” and condemned in no uncertain terms the court’s “contempt for basic principles of agency deference.” Brief for Amicus Curiae Wash. Legal Found. in Support of the Petition for Certiorari at 2, *Gen. Motors Corp.*, 540 U.S. 1068 (No. 03-165). WLF attacked each of the three reasons the Federal Circuit gave for affording no weight to the Cost Accounting Standards Board (CASB) staff documents: that the documents were written by CASB’s associate director and were not representative of the views of the agency at large; that the documents “were not [formal interpretations] published by the Board to aid the interpretation of CAS 413”; and that the documents were written nine months after the issuance of CAS 413. *Id.* at 5–7. Especially relevant here, WLF argued that the informality of the documents did not affect their weight under *Auer*, because “while this Court has recently refused to afford full *Chevron* deference to an agency interpretation of a *statute* on the ground that the interpretation is insufficiently formal . . . it has never afforded anything less than full *Seminole Rock* deference to an informal agency interpretation of its own *regulations*.” *Id.* at 6 (citing *Auer v. Robbins*, 519 U.S. 452, 461–63 (1997)); *see also id.* at 7 (“[I]n *Auer*, the agency’s interpretation came only in an *amicus* brief filed at the Court’s request, long after the promulgation of the relevant regulation.”). WLF’s contention here that the informality of agency interpretations does not lessen the amount of deference they are owed is at odds with its later insistence in *Christopher* that no deference should be accorded to any agency interpretation that was not issued through the formal process of notice-and-comment rule-making.
104. Brief of Wash. Legal Found. et al. as Amici Curiae in Support of Respondent, *supra* note 103, at 3.

effort to justify its new litigating position and policy preference.”<sup>105</sup> WLF concludes that “allowing regulatory agencies to freely change their interpretations of regulations and statutes, without the formal protections of notice-and-comment rulemaking, threatens to significantly undercut the predictability that has long been a hallmark of our common law system.”<sup>106</sup>

The NFIB also advocated drawing clear lines on the limits of *Auer* deference. And, as did the Chamber, it invoked the parroting exception to *Auer* deference: “DOL’s position is not aimed at interpreting an ambiguous regulation” because the ambiguity “instead lies in the statutory language, which is merely reiterated by DOL’s implementing regulations.”<sup>107</sup>

PhRMA likewise aligned itself with the Chamber, WLF, and NFIB, arguing that “when an agency proffers a statutory interpretation in an amicus brief, without going through notice-and-comment rulemaking, it is not entitled to deference under either *Chevron* or *Auer*.”<sup>108</sup> Moreover, deference would “upset[] settled expectations by departing abruptly and without explanation from the Department’s long-established flexible definition of sales.”<sup>109</sup> Consistency is key, according to PhRMA, because “an unexplained departure from an agency’s longstanding interpretation of its regulation is ‘likely to reflect the agency’s reassessment of wise policy rather than a reassessment of what the agency itself originally meant.’” And “regulated entities structure their affairs on the assumption that an agency will not suddenly and without explanation abandon its long-held views.”<sup>110</sup>

PhRMA also made vehement arguments against *Auer* deference in an amicus brief it submitted in support of a certiorari petition to the U.S. Supreme Court in *In re Novartis Wage & Hour Litigation*.<sup>111</sup> PhRMA took issue with the Second Circuit’s ruling that a Department

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105. *Id.* at 9.

106. *Id.* at 2.

107. Brief of Nat’l Fed’n of Indep. Bus. Small Bus. Legal Ctr. as Amicus Curiae in Support of the Respondent at 22, *SmithKline Beecham*, 132 S. Ct. 2156 (No. 11-204).

108. Brief of Pharm. Research & Mfrs. of Am. as Amicus Curiae in Support of Respondent at 4, *SmithKline Beecham Corp.*, 132 S. Ct. 2156 (No. 11-204). According to PhRMA, *Chevron* deference was not warranted because an interpretation announced in an amicus brief does not go through notice and comment rulemaking. And *Auer* deference was not warranted because the regulation merely parrots the statute. *Id.*

109. *Id.*

110. *Id.* at 31 (quoting *Dismas Charities, Inc. v. U.S. Dep’t of Justice*, 401 F.3d 666, 682 (6th Cir. 2005)).

111. 611 F.3d 141 (2d Cir. 2010), *abrogated by SmithKline Beecham*, 132 S. Ct. 2156.

of Labor (DOL) amicus brief, in which the agency announced for the first time that pharmaceutical sales representatives are not exempt from the FLSA's overtime pay requirements, was entitled to "controlling" deference under *Auer*.<sup>112</sup> PhRMA characterized the Second Circuit's application of *Auer* in its decision as "extreme," because "[i]n focusing only on the Department's interpretations on this appeal, and turning a blind eye to the dramatic change in position that the interpretations reflect, the Second Circuit allowed the Department to undo regulations promulgated through notice-and-comment rulemaking and engineer a revolution in FLSA jurisprudence via the expedient of an unsolicited *amicus* brief."<sup>113</sup> But PhRMA went beyond the application of *Auer* deference in this case to criticize the doctrine more generally. It claimed that "the *Auer* line of cases has generated confusion," and that "[t]he proper scope of deference to an agency's interpretation of its regulations is an important question meriting certiorari in its own right."<sup>114</sup> PhRMA advocated for lesser or no deference to be accorded in cases where an agency has issued inconsistent interpretations of its regulations or where an agency invokes deference to attempt to circumvent the rulemaking process.<sup>115</sup>

## 2. Steadfast Resistance

What perhaps might be obscured amidst this backdrop of business groups' oscillating positions on agency deference is that the Chamber of Commerce and NFIB have steadfastly resisted agency deference. Indeed, these groups have waged a consistent, sustained attack on *Auer* deference, even when confronted with sympathetic agency views in a particular case.

As discussed above, the Chamber resisted deference to the Department of Labor in *Auer*. But it did so by attempting to carve out an inconsistency exception to agency deference; namely, where the agency has put forth varying interpretations, none should be entitled to deference.<sup>116</sup> In *Christopher v. SmithKline Beecham Corp.*, the Chamber mounted the beginnings of a broad-scale attack on *Auer* deference. The Chamber raised a normative objection to such deference, arguing that

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112. See Brief of Pharm. Research & Mfrs. of Am. (PhRMA) as Amicus Curiae in Support of Petitioner at 3, *In re Novartis Wage & Hour Litig.*, 611 F.3d 141 (No. 10-460) (criticizing the Second Circuit's application of *Auer* deference to an amicus brief that dramatically changed Department of Labor policy).

113. *Id.* (internal quotation marks omitted).

114. *Id.* at 3-4.

115. *Id.* at 5-12.

116. Brief Amici Curiae of the Chamber of Commerce of the U.S. & the Fair Labor Standards Act Reform Coal. in Support of Respondents, *supra* note 92, at \*16 n.7.

“granting controlling deference on issues not remotely addressed during a rulemaking would perversely invite agencies to avoid clear and comprehensive regulations accompanied by notice and comment and instead adopt major policy changes via amicus brief.”<sup>117</sup> The Chamber drew a direct parallel to the *Mead* doctrine, which limits *Chevron* deference to situations where the agency has interpreted a statute after “engag[ing] in the sort of procedural formalities that indicate the agency was exercising the authority ‘to make rules carrying the force of law.’”<sup>118</sup> And the Chamber argued that *Auer* too must be limited lest agencies circumvent *Mead* by “simply pass[ing] a regulation parroting the statute, and then invok[ing] controlling deference under *Auer* to its interpretation of its own regulation.”<sup>119</sup>

At the time of *Christopher*, the NFIB was also seeking to curtail or limit *Auer* deference. The NFIB argued that “[w]hile deference to an agency’s interpretations may be appropriate in some circumstances, clear bounds need to be set to ensure that critical regulatory changes are not permitted to occur absent notice-and-comment procedures.”<sup>120</sup> At that time, the NFIB was starting to build an edifice of policy justifications for a wider-scale attack on *Auer*. Significantly, the NFIB claimed that “[p]ermitting agencies such as DOL to announce new policies through obscure methods, such as *amicus* filings, would have a devastating impact on industries,” including “massive retroactive liability.”<sup>121</sup> NFIB further claimed that allowing agencies to “informally interpret statutory language” creates the risk that the “agency’s new position will have a detrimental sweeping effect across any entire industry.”<sup>122</sup> NFIB also foreshadowed what would become its paramount concern regarding notice to the regulated community: “APA procedures guarantee that the regulated community is put on notice of proposed new regulations and changes to existing regulations” and that “the regulated community is given the opportunity to provide the agency with the benefit of its hands-on knowledge regarding how the regulatory changes will impact them.”<sup>123</sup>

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117. Brief of Chamber of Commerce of the U.S. as Amicus Curiae at 5–6, *Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156 (2012) (No. 11-204).

118. *Id.* at 20–21, (quoting *United States v. Mead Corp.*, 533 U.S. 218, 226–27).

119. *Id.* at 21.

120. Brief of Nat’l Fed’n of Indep. Bus. Small Bus. Legal Ctr. as Amicus Curiae in Support of the Respondent, *supra* note 107, at 23, *SmithKline Beecham*, 132 S. Ct. 2156 (No. 11-204).

121. *Id.* at 25–26.

122. *Id.* at 24 (emphasis omitted).

123. *Id.*



But of course, in both *Auer* and *Christopher*, the DOL's position was adverse to that of the relevant business communities. In this respect, *Decker v. Northwest Environmental Defense Center*,<sup>124</sup> wherein the agency position favored business interests, is a pivotal case that tests the nature of principled opposition to *Auer* deference. In *Decker*, the Northwest Environmental Defense Center sued the Oregon State Forester and several logging companies, alleging that they violated the Clean Water Act by using ditches and channels to funnel storm water runoff into nearby rivers without a permit.<sup>125</sup> The EPA filed an amicus brief in support of the Oregon State Forester and logging companies, interpreting its regulations as not requiring permits for the runoff discharges at issue.<sup>126</sup> The Ninth Circuit Court of Appeals, however, ruled against the EPA and in favor of the Northwest Environmental Defense Center.<sup>127</sup> In its amicus brief before the U.S. Supreme Court, the EPA argued that, in the face of an ambiguous Rule, "the court of appeals should have deferred under *Auer* to EPA's interpretation of its own Rule provided in the government's amicus brief."<sup>128</sup>

Before the U.S. Supreme Court, several business groups—including the American Forest Resource Council, the National Alliance of Forest Owners, and the Chamber of Commerce—submitted amicus briefs. As might be expected, two of the business groups advocated deference to the EPA, which supported the relevant business community's position. The American Forest Resource Council, a "nonprofit corporation that represents the forest products industry," argued that the Ninth Circuit decision should be reversed because it "failed to give deference to the [EPA's] long-standing interpretation" of its Rule.<sup>129</sup> And the National Alliance of Forest Owners, a "trade association representing owners and managers of over 79 million acres of private forests in 47 states," likewise criticized the Ninth Circuit for "fail[ing] to afford *Auer* deference to EPA's longstanding construction of its Rule."<sup>130</sup>

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124. 133 S. Ct. 1326 (2013).

125. *Id.* at 1328–29.

126. Brief for the United States as Amicus Curiae Supporting Petitioners at 3, *Decker*, 133 S. Ct. 1326 (Nos. 11-338, 11-347).

127. *Nw. Env'tl. Def. Ctr. v. Brown*, 640 F.3d 1063, 1087 (9th Cir. 2011).

128. Brief for the United States as Amicus Curiae at 12, *Decker*, 133 S. Ct. 1326 (Nos. 11-338, 11-347).

129. Brief of Am. Forest Res. Council, Pub. Lands Council, Nat'l Cattlemen's Beef Ass'n, Mont. Wood Prods. Ass'n Inc., Ark. Forestry Ass'n, Fed. Forest Res. Coal., Inc. & Intermountain Forest Ass'n as Amici Curiae in Support of Petitioners at 1, 7, *Decker*, 133 S. Ct. 1326 (Nos. 11-338, 11-347).

130. Brief for Nat'l All. of Forest Owners et al. as Amici Curiae in Support of Petitioners at 1, 27, *Decker*, 133 S. Ct. 1326 (Nos. 11-338, 11-347). The National Alliance of Forest Owners conceded that "[s]uch deference is to be denied in certain circumstances," but concluded that "there was no reason to

Here, significantly, the Chamber took a different tack. Notwithstanding the fact that the EPA's interpretation supported the Chamber's position, the Chamber explicitly disavowed the agency's claim to deference and based its arguments on independent legal grounds. The Chamber argued that the rule unambiguously exempts logging ditches and channels from the permit requirement and thus claimed that the Ninth Circuit's interpretation to the contrary was erroneous.<sup>131</sup> The Chamber went out of its way to disavow the EPA's reasoning, stating that "[w]hile the United States ultimately reaches the correct outcome . . . its analysis is plainly wrong."<sup>132</sup> According to the Chamber, *Auer* deference had no role to play in the analysis and it warned that to "defer to the agency's position [here] would be to permit the agency, under the guise of interpreting a regulation, to create de facto a new regulation."<sup>133</sup>

The Chamber transitioned into a full-scale attack on *Auer*, emphasizing the "perverse incentives propelling [agencies] toward crafting ambiguous rules when they are asked . . . to implement statutes through regulations" and the "related danger" whereby "[e]ven where a regulation itself is not ambiguous, an agency might well strain to manufacture a false, *post hoc* ambiguity and thereby create administrative

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deny it here." *Id.* (citing *SmithKline Beecham*, 132 S. Ct. at 2166). And, in a footnote, the National Alliance also pointed out that the Ninth Circuit had failed to "articulate why EPA's interpretation of ambiguous terms such as 'nonpoint source' did not warrant deference under *Chevron*." *Id.* at 13 n.5. The NFIB brief did not address *Auer*, but argued that the Court should accord *Chevron* deference to the EPA's interpretation of the Clean Water Act. Brief of Amicus Curiae of The Nat'l Fed'n of Indep. Bus. Small Bus. Legal Ctr. at 3, *Decker*, 133 S. Ct. 1326 (Nos. 11-338, 11-347) ("[T]he EPA's Silviculture Rule deserves *Chevron* deference because the agency provided a reasoned explanation for exempting timber harvesting operations from NPDES permitting requirements consistent with the principles of federalism entailed in the Ninth and Tenth Amendments."). NFIB did caution that *Chevron* "does not vest [an agency] with unbridled discretion to resolve ambiguities in any conceivable manner. The agency's interpretation must be *reasonable*, and must comport with the background principles of our constitutional system." *Id.* It did state unequivocally, however, that "*Chevron* deference is not paramount to . . . judicial abdication." *Id.* at 5.

131. Brief of Amicus Curiae Chamber of Commerce of the U.S. in Support of Petitioners at 14–18, *Decker*, 133 S. Ct. 1326 (Nos. 11-338, 11-347).

132. *Id.* at 19.

133. *Id.* (quoting *Christensen v. Harris Cty.*, 529 U.S. 576, 588 (2000)). *See also id.* (arguing that because "*Auer* deference is warranted only when the language of the regulation is ambiguous," even the "EPA has no discretion to read the [Rule] as the Ninth Circuit did" (quoting *Christensen*, 529 U.S. at 588)). Moreover, the Chamber argued that the EPA's "shifting positions in this litigation undermine any agency deference that [it] might otherwise be entitled to claim." *Id.* at 20 (citing *SmithKline Beecham*, 132 S. Ct. at 2167–68).

flexibility that allows the agency to dispense with notice and comment before effecting regulatory changes.”<sup>134</sup>

The Chamber continued its concerted assault on *Auer* in *Perez v. Mortgage Bankers Ass’n*.<sup>135</sup> *Perez* was yet another case addressing the

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134. *Id.* at 21–22 (citing *SmithKline Beecham*, 132 S. Ct. at 2168).

135. 135 S. Ct. 1199 (2015). The Chamber and NFIB have, moreover, waged this frontal assault on *Auer* in the lower courts. For example, in *Rivera v. Peri & Sons Farms Inc.*, 755 F. 3d 892 (9th Cir. 2013), cert denied, 134 S. Ct. 2819 (2014), the Chamber joined a coalition brief urging the U.S. Supreme Court to grant certiorari to overturn the Ninth Circuit’s decision giving deference to the DOL’s interpretation of the FLSA as requiring employers to reimburse foreign workers’ pre-employment travel and immigration expenses. See Brief of the Chamber of Commerce of the U.S. & Nat’l Mining Ass’n as Amici Curiae in Support of Petitioner at 3–6, *Rivera*, 134 S. Ct. 2819 (No. 13-950) (asking the U.S. Supreme Court to grant certiorari specifically to reconsider *Auer*). The Chamber characterized *Auer* deference as a “doctrine [that] arose from a single sentence in the 1945 *Seminole Rock* decision, which was then cited and applied in subsequent cases without any examination of the rule’s underlying merits.” *Id.* at 3. It asked the Court to “grant certiorari to squarely address the ongoing validity of the *Auer* doctrine,” noting that several Justices had recently “called for a reconsideration of *Auer* in an ‘appropriate case’” and deeming this to be that appropriate case. *Id.* at 3–4. It explained that “[t]he scope of such deference is tremendously important to the business community, as administrative agencies have increasingly attempted to make policy through informal guidance rather than notice-and-comment rulemaking.” *Id.* at 4. NFIB likewise seized the opportunity to attack *Auer*. To NFIB, the case “squarely presents the issue of whether the judiciary is required to cede its power to interpret administrative regulations to administrative agencies.” Brief of Amici Curiae Ctr. for Constitutional Jurisprudence, Cato Inst. & Nat’l Fed’n of Indep. Bus. Small Bus. Legal Ctr. in Support of Petitioner at 2, *Rivera*, 134 S. Ct. 2819 (No. 13-950). NFIB’s brief revisits familiar anti-*Auer* arguments: the doctrine is “contrary to [the] fundamental principles of separation of powers” and represents “an abdication of [the judiciary’s] duty.” *Id.* at 2–3 (quoting *Talk Am., Inc. v. Mich. Bell Tel. Co.*, 131 S. Ct. 2254, 2266 (2011) (Scalia, J., concurring)). It rejects the premise that “the agency, the drafter of the regulation, has some special insight into its intent when enacting the regulation” as irrelevant for the purposes of the deference debate because “courts are bound by the language of the laws, not by ‘the unexpressed intention of those who made’ it.” *Id.* at 10 (citing *Decker*, 133 S. Ct. at 1339–40 (Scalia, J., dissenting in relevant part)). It argues that “[a]ctive judicial review incentivizes agencies to promulgate unambiguous regulations that give fair notice to the regulated community.” *Id.* at 11. The brief concludes with a section summarizing all of the opinions in which the Justices have voiced doubts about *Auer*. *Id.* at 13–15. See also Brief of Amici Curiae Se. Legal Found., Nat’l Fed’n of Indep. Bus. Small Bus. Legal Ctr., The Buckeye Inst., The Beacon Ctr. of Tenn. & Thomas P. Gross in Support of Petitioner at 5, *Flytenow, Inc. v. Fed. Aviation Admin.*, 137 S. Ct. 618 (2017) (No. 16-14) (urging the Court to grant certiorari not only to resolve the circuit split on the specific question of the deference owed to agency interpretations of common law terms, but also because “this case also provides an opportunity to address the doubts raised by several members of this Court as to the continued validity of *Auer*”).

scope of an exception to the FLSA overtime rule. The Department of Labor issued an opinion letter in 2006 stating that mortgage loan officers fell within the “administrative employee” exception to the overtime rule, then subsequently reversed its position in a second interpretation in 2010.<sup>136</sup> The Mortgage Bankers Association sued the DOL for changing its interpretation without going through notice and comment rule-making, and the D.C. Circuit Court of Appeals ruled in favor of Mortgage Bankers Association.<sup>137</sup> Business groups filed six briefs in support of Mortgage Bankers.<sup>138</sup>

Among those groups was the Chamber, which remained steadfast in its increasingly vociferous opposition to *Auer*.<sup>139</sup> The Chamber argued that “[u]nder *Auer*, agencies can thwart meaningful feedback by promulgating vague legislative regulations and then interpreting those regulations as they see fit, knowing that courts must accept those interpretations as long as they are not patently incompatible with the statutory or regulatory text.”<sup>140</sup> The Chamber’s brief is replete with a parade of horrors, or at least “serious concerns” raised by *Auer*: the threat to

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136. Dep’t of Labor, Wage & Hour Div., FLSA2006-11, Opinion Letter on Mortgage Loan Officers Under the FLSA (Mar. 31, 2006); DEP’T OF LABOR, WAGE & HOUR DIV., ADMINISTRATOR’S INTERPRETATION NO. 2010-1 (Mar. 24, 2010).

137. *Mortg. Bankers Ass’n v. Harris*, 720 F.3d 966, 968 (D.C. Cir. 2013).

138. Brief of the Nat’l Mining Ass’n as Amicus Curiae Supporting Respondent, *Perez*, 135 S. Ct. 1199 (Nos. 13-1041, 13-1052); Brief for the Am. Hosp. Ass’n, Ass’n of Am. Med. Colls. & Healthcare Fin. Mgmt. Ass’n as Amici Curiae Supporting Respondent, *Perez*, 135 S. Ct. 1199 (Nos. 13-1041, 13-1052); Brief of Amici Curiae Util. Air Reg. Grp. & American Forest & Paper Ass’n in Support of Respondent, *Perez*, 135 S. Ct. 1199 (Nos. 13-1041, 13-1052); Brief of Amici Curiae Chamber of Commerce of the U.S., Am. Fuel & Petrochemical Mfrs., Am. Health Care Ass’n, Bus. Roundtable, Nat’l Ass’n of Mfrs. & Secs. Indus. & Fin. Mkts. Ass’n in Support of Respondents, *Perez*, 135 S. Ct. 1199 (Nos. 13-1041, 13-1052); Brief for Nat’l Fed’n of Indep. Bus., Am. Farm Bureau Fed’n, Am. Petroleum Inst., Nat’l Ass’n of Home Builders & Retail Litig. Ctr. as Amici Curiae Supporting Respondents, *Perez v. Mortg. Bankers Ass’n*, 135 S. Ct. 1199 (2015) (Nos. 13-1041, 13-1052); Brief of Amicus Curiae Quicken Loans, Inc. in Support of Respondent *Mortg. Bankers Ass’n*, *Perez v. Mortg. Bankers Ass’n*, 135 S. Ct. 1199 (2015) (Nos. 13-1041, 13-1052).

139. The Chamber and NFIB were joined in their efforts to overrule *Auer* by several additional business groups filing amicus briefs. *See, e.g.*, Brief of Amici Curiae Util. Air Reg. Grp. & American Forest & Paper Ass’n in Support of Respondent, *supra* note 138, at 13–15 (urging the Court to overrule *Auer/Seminole Rock* and thus hold that if an agency interprets its rules outside the notice-and-comment process, that interpretation is entitled to only *Skidmore* respect in accordance with its “power to persuade”).

140. Brief of Amici Curiae Chamber of Commerce of the U.S. et al. in Support of Respondents, *supra* note 138, at 6, 13–14.

separation of powers;<sup>141</sup> the concern that “[a]gencies may not have special insight into what their regulations say, and their policy expertise is arguably irrelevant to the purely interpretive task of figuring out what the law is”; and the concern that “*Auer* deference ‘creates a risk that agencies will promulgate vague and open-ended regulations that they can later interpret as they see fit, thereby frustrating the notice and predictability purposes of rulemaking.’”<sup>142</sup> The Chamber raises an issue of particular concern to businesses, namely that giving deference to agencies’ interpretive about-faces “would threaten the reliance interests of those who, because of the agency’s ambiguous legislative regulations, must structure their affairs around interpretive rules.”<sup>143</sup>

As might be expected, several other business groups, including the NFIB,<sup>144</sup> endorsed the D.C. Circuit’s *Paralyzed Veterans* doctrine, framing the doctrine as a way to prevent agencies from significantly changing interpretations to the detriment of businesses’ reliance interests and then receiving *Auer* deference for those interpretations.<sup>145</sup> The National

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141. *Id.* at 14–15 (citing John F. Manning, *Constitutional Structure and Judicial Deference to Agency Interpretations of Agency Rules*, 96 COLUM. L. REV. 612, 638–54 (1996)).

142. *Id.* (quoting *Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156, 2168 (2012)).

143. *Id.* at 21. The Chamber elaborated: “Although the Due Process Clause and administrative law protections such as arbitrary and capricious review would guard against the *most* egregious threats to reliance interests, the high barriers posed by some of these doctrines might not shield reliance interests in the ordinary case where an agency changes its mind to the detriment of the regulated parties.” *Id.* at 21–22.

144. Brief for Nat’l Fed’n of Indep. Bus., Am. Farm Bureau Fed’n, Am. Petroleum Inst., Nat’l Ass’n of Home Builders & Retail Litig. Ctr. as Amicus Curiae Supporting Respondents, *supra* note 138, at 21–22.

145. *See, e.g.*, Brief of Amicus Curiae Quicken Loans Inc. in Support of Respondent Mortg. Bankers Ass’n, *supra* note 138, at 16 (praising *Paralyzed Veterans* as “protect[ing] interests of regulated entities by requiring administrative agencies . . . to comply with the APA before substantively changing a prior definitive interpretation”); Brief for the Am. Hosp. Ass’n, Ass’n of Am. Med. Colls. & Healthcare Fin. Mgmt. Ass’n as Amici Curiae Supporting Respondent, *supra* note 138, at 4 (similarly advocating for the *Paralyzed Veterans* doctrine).

The Washington Legal Foundation’s amicus brief primarily focused on persuading the Court to uphold the D.C. Circuit’s *Paralyzed Veterans* rule, which WLF characterized as “an effective tool for distinguishing those rule revisions that are purely interpretative and do not have the force of law (and are thus exempt from the APA’s notice-and-comment requirements) from substantive rule revisions that are subject to those requirements.” Brief of Wash. Legal Found. & Allied Educ. Found. as Amici Curiae in Support of Respondent at 2, *Perez*, 135 S. Ct. 1199 (Nos. 13-1041, 12-1052). WLF expressed concern that, if it were overturned, “some federal agencies will seek to evade that procedural requirement by adopting *de facto* amendments to substantive rules under the guise of merely ‘re-interpreting’ those rules.” *Id.*

Mining Association (“NMA”) urged the Court to adopt a rule whereby “[a]n agency that wants to reverse itself and dispense with notice and comment must also abandon any claim to deference, justify its departure from the prior interpretation, and refrain from applying the new interpretation retroactively.”<sup>146</sup> Recall that NMA was one of the groups that urged deference to the expertise of the Corps and the EPA in *Coeur Alaska*. Granted, *Coeur Alaska* did not entail an agency’s change in position. Even so, in *Perez*, the NMA expressed more general distaste for *Auer*: “[T]he same federal government that today tells the Court that agency interpretations are harmlessly non-binding will tomorrow demand that the courts treat such interpretations as binding. And under current doctrine, the courts will generally agree, as long as the agency stays within the ‘considerable legal leeway’ that *Auer* deference extends.”<sup>147</sup>

### *B. Implications for Federal Preemption*

In the federal preemption context, business groups tout the institutional advantages that the FDA has over the state tort law system as a regulatory mechanism. The Product Liability Advisory Council (“PLAC”) summarizes the mainstream position, namely that the “judge, the jury, and the plaintiff in an individual case focus only on the particular matter before the court” and that “[i]n litigation, each lawyer’s obligation is solely to represent his or her client zealously.”<sup>148</sup> Accordingly, the “FDA, not lawyers for individual litigants, has the job of protecting the public health.”<sup>149</sup>

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WLF invoked *Auer* in an interesting way to bolster its contention that the Department of Labor’s challenged position—that mortgage loan officers are not exempt from the FLSA’s overtime provisions—was a substantive rule that was subject to notice-and-comment requirements. WLF pointed out that in other recent FLSA litigation, the Department had filed amicus briefs arguing that its position was entitled to *Auer* deference. *Id.* at 21–22. But because “this Court has made clear that interpretive rules are not entitled to *Auer* deference,” WLF reasoned, the Department’s “assertion that [its rule] is entitled to *Auer* deference is a strong indication that [it] deems [the rule to be] a substantive rule, not an interpretive rule.” *Id.* at 22. Thus, instead of criticizing the *Auer* doctrine, WLF assumed its legitimacy in using it to prove a corollary point.

146. Brief of the Nat’l Mining Ass’n as Amicus Curiae Supporting Respondent, *supra* note 138, at 26. According to the NMA, the “Court has already laid the groundwork for such a rule.” *Id.* at 27–28 (citing *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994); *United States v. Mead Corp.*, 533 U.S. 218, 234–35 (2001)).

147. *Id.* at 11 (emphasis omitted).

148. Brief of Prod. Liab. Advisory Council, Inc. as Amicus Curiae in Support of Respondent, *supra* note 18, at 22.

149. *Id.*

In making pro-preemption arguments, amici repeatedly urge the Court to afford substantial weight to the views of an agency that state regulation interferes with the federal regulatory scheme that the agency has been charged with administering. Business groups have tended to invoke *Auer* (and *Chevron*) deference to support preemption, particularly in the FDA context.

The Chamber of Commerce has weighed in on a large number of preemption cases in the federal courts of appeals and U.S. Supreme Court.<sup>150</sup> Neither the Chamber nor PhRMA has wavered from its pro-

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150. The Chamber of Commerce has been involved in a large number of federal preemption cases, taking the following positions in these cases: *Metro. Milwaukee Ass'n of Commerce v. Milwaukee Cty.*, 431 F.3d 277 (7th Cir. 2005) (urging the court to find that the National Labor Relations Act preempted a county ordinance that required certain county-paid patient transport and patient care contractors to enter into labor peace agreements); *Chamber of Commerce of the U.S. v. Brown*, 554 U.S. 60 (2008) (arguing that a California law prohibiting employers who receive more than \$10,000 in state funds annually from using those funds “to assist, promote, or deter union organizing” was preempted by the National Labor Relations Act); *Rowe v. N.H. Motor Transp. Ass'n*, 552 U.S. 364 (2008) (urging the court to affirm the district court’s judgment that Maine’s effort to regulate motor carrier traffic where it involved the transport of tobacco products is preempted by the Motor Carrier Act and the Federal Aviation Administration Authorization Act); *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387 (7th Cir. 2010) (urging the Seventh Circuit to hold that a state law failure to warn claim is conflict-preempted by the FDA’s rejection of additional warnings for a class of anti-depressant drugs); *Kurns v. R.R. Friction Prods. Corp.*, 132 S. Ct. 1261 (2012) (arguing that the Federal Railroad Safety Acts preempted state-law-based tort claims relating to injury sustained during the manufacture of locomotive equipment); *Am. Trucking Ass'ns, Inc. v. City of Los Angeles*, 133 S. Ct. 2096 (2013) (arguing that the Federal Aviation Administration Authorization Act preempted a municipal government program barring federally licensed motor carriers from access to a port); *Entergy Nuclear Vt. Yankee, LLC v. Shumlin*, 733 F.3d 393 (2d Cir. 2013) (asking the court to find that the Atomic Energy Act preempted conflicting Vermont state regulations); *Am. Tort Reform Ass'n v. Occupational Safety & Health Admin.*, 738 F.3d 387 (D.C. Cir. 2013) (urging the court to vacate OSHA’s amendments to the Hazard Communication Standard announcing that state tort claims were no longer preempted); *Am.’s Health Ins. Plans v. Hudgens*, 742 F.3d 1319 (11th Cir. 2014) (urging the court to hold that a Georgia law imposing additional reporting requirements on self-funded insurance plans was preempted by the Employee Retirement Income Security Act); *Nw., Inc. v. Ginsberg*, 134 S. Ct. 1422 (2014) (arguing that state law claims for breach of implied-by-law covenants are preempted by the Airline Deregulation Act); *Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378 (2015) (arguing that the Supremacy Clause confers a private right of action to enjoin states from enforcing preempted state law); *Penske Logistics, LLC v. Dilts*, 135 S. Ct. 2049 (2015) (urging the U.S. Supreme Court to grant a petition for certiorari to clarify that the Federal Aviation Administration Authorization Act preempted California’s meal and rest break laws as applied to motor carriers); *Little v. Louisville Gas & Elec. Co.*, 805 F.3d 695 (6th Cir. 2015) (asking the court to hold that the Clean Air Act preempted state common law nuisance claims); *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936

preemption view. But with respect to reliance on *Auer* deference, there may be some trace evidence of a shifting away. The Chamber did not weigh in on *PLIVA*, but it did intervene (in a joint amicus brief with PhRMA) in *Mutual Pharmaceutical*, where it argued for preemption with nary a mention of *Auer*.

1. Traditional Business Position: Deference to FDA Supports  
Pro-Preemption View

The traditional pro-preemption business position is consistently put forth by PLAC, a “nonprofit association with more than 120 corporate members representing a broad cross-section of American and international product manufacturers.”<sup>151</sup> Time and again, PLAC has invoked deference to the FDA in advocating preemption of state tort claims against medical device and drug manufacturers.

In *Riegel v. Medtronic, Inc.*, PLAC cites various FDA statements to bolster its claim that “[i]n enacting the express preemption provision in the MDA, Congress determined that imposition of state requirements in addition to or different from federal regulation would undermine public health.”<sup>152</sup> PLAC draws attention to the fact that the “FDA has stated in [the U.S. Supreme Court], in Courts of Appeals, and in the preamble to regulations, [that] allowing state judges and juries to second-guess the FDA’s approval of [medical devices], or to dictate different requirements than FDA has imposed, impedes FDA’s ability to fulfill its mandate in furtherance of public health.”<sup>153</sup> PLAC points to the FDA’s preemption preamble to its drug labeling regulation, which states that “[s]tate-law attempts to impose additional warnings lead to labeling that does not accurately portray a product’s risks’ and

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(2016) (urging the U.S. Supreme Court to hold that a Vermont law that imposed record keeping and reporting obligations on self-employed plans beyond those required by the Employee Retirement Income Security Act was preempted); *Cook v. Dow Chem. Co.*, 136 S. Ct. 2055 (2016) (asking the Supreme Court to grant a petition for certiorari and find that the Price-Anderson Act preempted state law claims by a plaintiff who suffered a nuclear-related injury); *Johnson & Johnson v. Reckis*, 136 S. Ct. 896 (2016) (asking the U.S. Supreme Court to grant a petition for certiorari and hold that the FDA’s rejection of warning language proposed in a Citizen Petition is “clear evidence” sufficient to preempt state tort failure to warn claims); *Puerto Rico v. Franklin Ca. Tax-Free Trust*, 136 S. Ct. 1938 (2016) (arguing that the federal Bankruptcy Code preempted a Puerto Rico statute creating a mechanism for Puerto Rico’s struggling public utilities to restructure their debts).

151. Brief of Prod. Liab. Advisory Council, Inc. as Amicus Curiae in Support of Respondent, *supra* note 18, at 1.

152. *Id.* at 4.

153. *Id.*



threaten [the] ‘FDA’s statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs.’”<sup>154</sup>

PLAC has likewise been a staunch advocate for federal preemption in the prescription drug context. In *Wyeth*, PLAC explicitly calls for the Court to accord deference to FDA determinations that state law could threaten to upset a federal regulatory scheme that the agency has been tasked with implementing.<sup>155</sup> PLAC claims the “FDA’s interpretation of the FDCA is clear” that FDA approval of labeling preempts contrary state law, and that in “reaching the opposite conclusion . . . [t]he Vermont Supreme Court’s failure to defer to the FDA’s interpretation of the FDCA is contrary to [U.S. Supreme Court] precedent.”<sup>156</sup> PLAC is emphatic that the FDA’s position is “reasonable and entitled to full deference.”<sup>157</sup> Nor, PLAC argues, should “[t]he fact that the FDA has articulated its preemption determination in a regulatory preamble and a series of amicus briefs . . . diminish the deference owed that determination” because an “agency’s conclusion that federal law preempts state law may properly be communicated in ‘regulations, *preambles*, interpretive statements and responses to comments.’”<sup>158</sup> Moreover, citing *Auer*, PLAC argues that the fact that the “‘agency’s fair and considered judgment on the matter in question’ is conveyed ‘in the form of a legal brief’ does not make the agency’s view ‘unworthy of deference.’”<sup>159</sup>

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154. *Id.* at 22 (quoting Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006)).

155. See Brief of Amicus Curiae Prod. Liab. Advisory Council, Inc. in Support of Petitioner at 4, *Wyeth v. Levine*, 555 U.S. 555 (2009) (No. 06-1249).

156. *Id.* at 30. PLAC cites *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 714–15 (1985), for the proposition that when, “as in the case of the FDA, Congress has delegated authority to an expert federal agency to implement and enforce a federal regulatory scheme, the agency’s determination that state law threatens to upset federal objectives ‘is dispositive . . . unless either the agency’s position is inconsistent with clearly expressed congressional intent, or subsequent developments reveal a change in that position.’” *Id.* at 31 (omission in original).

157. *Id.* at 32.

158. *Id.* (quoting *Hillsborough Cty.*, 471 U.S. at 718).

159. *Id.* (quoting *Auer v. Robbins*, 519 U.S. 452, 462 (1997)). PLAC also disputed the lower court’s rejection of *Chevron* deference. The Vermont Supreme Court disregarded the FDA’s interpretation of the FDCA in part because it believed that “Congress, in a savings clause, expressly limited implied preemption in the drug context to situations in which compliance with federal and state law is a physical impossibility,” and “[*Chevron*] deference to an agency’s interpretation is appropriate only when a statute is silent or ambiguous with respect to the specific issue the agency has considered.” *Id.* at 33 (internal quotation marks omitted). PLAC argued that the Vermont Supreme Court’s belief was wrong because it was rooted in a misinterpretation of the U.S. Supreme

Other affected industry groups have also weighed in on federal preemption before the U.S. Supreme Court. In *Riegel*, the Advanced Medical Technology Association and Medical Device Manufacturers Association, whose members consist of medical device manufacturers, characterize the FDA as “an expert federal agency,” which “Congress has charged . . . with striking a careful balance of public health objectives.”<sup>160</sup> It claims that the FDA has a “unique vantage point” since it “‘holds the only broad, cross-cutting knowledge’ and ‘experience with the totality of other applications,’ and also utilizes its knowledge of ‘the latest science.’”<sup>161</sup> In contrast, “lay juries are not institutionally well-equipped to make the kinds of nuanced risk-benefit calculations and scientific judgments Congress has charged FDA—as the expert federal agency—with making.”<sup>162</sup> In making this argument, the Association drew from an FDA amicus brief in which the FDA “cautioned that state common-law tort actions which ‘encourage, and in fact require, lay judges and juries to “second-guess” FDA’s balancing of the benefits and risks of a specific device, create pressures for “defensive labeling” . . . [and] result[] in scientifically unsubstantiated warnings and underutilization of beneficial treatments.’”<sup>163</sup>

Picking up this same theme of contrasting federal agency regulation with state tort liability, CropLife America, the American Chemistry Council, and Consumer Specialty Products Association, whose members consist of pesticide manufacturers, claim that “[c]onflicting or differing jury verdicts, which indisputably have a regulatory effect on a product’s manufacturer, can impede, impair, or destroy the national uniformity that Congress seeks to achieve under the auspices of expert and experienced federal agencies such as FDA and EPA.”<sup>164</sup> And they likewise extol regulation by agency experts, urging that “consumer protection is *enhanced* when highly experienced federal agencies, staffed by dedicated

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Court’s implied preemption doctrine, but did not otherwise contest the lower court’s explanation of the *Chevron* doctrine’s applicability. *Id.*

160. Brief of the Advanced Med. Tech. Ass’n (ADVAMED), DRI, MedMarc & the Med. Device Mfrs. Ass’n (MDMA) as Amici Curiae in Support of Respondent at 1, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (No. 06-179).

161. *Id.* at 9–10 (quoting FOOD & DRUG ADMIN., INNOVATION OR STAGNATION: CHALLENGE AND OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS 13 (2004), <https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/CriticalPathInitiative/CriticalPathOpportunitiesReports/UCM113411.pdf> [<https://perma.cc/Q86P-2V38>]).

162. *Id.* at 15–16.

163. *Id.* at 27 (quoting Letter-Brief of the United States as Amici Curiae at 25–26, *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (No. 02-4597)).

164. Brief of CropLife Am., Am. Chem. Council & Consumer Specialty Prods. Ass’n as Amici Curiae in Support of Respondent at 4, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (No. 06-179).

scientific experts, regulate products such as medical devices, drugs, and pesticides in a nationally uniform manner.”<sup>165</sup> In sum, the pesticide manufacturers conclude that the “substantial health, safety, environmental, and product performance benefits that nationally uniform, EPA-regulated product labeling affords to consumers, farmers, and professional pesticide applicators cannot be over-stated” and that the “same undoubtedly is true for nationally uniform medical device and drug labeling.”<sup>166</sup>

Groups such as PLAC do not have much interest in the *Auer* line of cases, so there is no way to gauge whether their pro-agency advocacy would hold up outside of the preemption context. But, significantly, groups such as PhRMA and the Chamber of Commerce do.

## 2. Whither Steadfast Resistance to *Auer*?

The Chamber and PhRMA have never wavered in their pro-preemption positions. But the enthusiasm with which they wield *Auer* deference in support may be wavering.

### *a. Auer Deference Wielded to Support Preemption*

In *Wyeth*, PhRMA, along with the Biotechnology Industry Organization (“BIO”)—whose “members are involved in research and development of innovative healthcare technologies”—submitted a brief advocating for *Auer* deference.<sup>167</sup> Both groups insisted that the Vermont Supreme Court misinterpreted the FDA’s drug labeling regulation as “grant[ing] manufacturers general permission to ‘add and strengthen warnings’ without prior FDA approval,” whereas “FDA has long interpreted its regulation as creating a limited exception that applies only to ‘concerns about *newly discovered* risks’ and ‘important *new information* about the safe use of a drug.’”<sup>168</sup> According to PhRMA and BIO, this FDA “interpretation of the substantive meaning of its own regulation is entitled to substantial judicial deference” under *Auer*.<sup>169</sup>

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165. *Id.* at 13.

166. *Id.* at 18.

167. Brief for PhRMA & BIO as Amici Curiae Supporting Petitioner, *supra* note 23, at 2.

168. *Id.* at 29–30 (citing New Drug and Antibiotic Regulations, 47 Fed. Reg. 46,622, 46,623, 46,635 (Oct. 19, 1982)).

169. *Id.* at 30. PhRMA and BIO also argue that “an agency’s determination that a state law poses an obstacle to achieving the purposes and objectives of federal law is also entitled to a degree of judicial deference.” *Id.* at 30 n.14 (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996) and *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000)).

Likewise, in *Fussman v. Novartis Pharmaceuticals Corp.*,<sup>170</sup> PhRMA squarely relied on *Auer* deference in an amicus brief urging the U.S. Supreme Court to grant certiorari to overturn a Fourth Circuit decision finding that state law failure to warn liability is not preempted by the FDA's authority.<sup>171</sup> After describing the FDA's label approval process, PhRMA argued that the "FDA's view that its CBE regulation permits a unilateral label change only when justified by new and significant information easily satisfies" the "plainly erroneous or inconsistent with the regulations" test for receiving *Auer* deference.<sup>172</sup>

Recall, however, that only three years later, PhRMA intervened as amicus in *Christopher*, joining forces with the Chamber and NFIB in resisting *Auer* deference.<sup>173</sup> Specifically, it argued that "when an agency proffers a statutory interpretation in an *amicus* brief, without going through notice-and-comment rulemaking, it is not entitled to deference under either *Chevron* or *Auer*."<sup>174</sup> Perhaps to reconcile this reliance on *Auer* with its prior position in *In re Novartis Wage & Hour Litigation*, PhRMA noted specifically in *Fussman* that the interpretation in this case "is the agency's longstanding and consistent view, dating back to the 1982 promulgation of the regulation."<sup>175</sup>

Another group to have struggled to reconcile its general anti-agency inclination with its reliance on agency deference arguments in preemption litigation is the Washington Legal Foundation ("WLF"). In 2006, the WLF issued a press release calling for deference to be given to an FDA statement of policy outlining the agency's pro-preemption position.<sup>176</sup> WLF "praised the [FDA] for issuing a policy statement indicating that manufacturers who label their drugs in accordance with

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170. 509 F. App'x 215 (4th Cir. 2013), *cert. denied*, 134 S. Ct. 88 (2013).

171. See Brief for Pharm. Research & Mfrs. of Am. as Amicus Curiae in Support of Petitioner, *Fussman*, 134 S. Ct. 88 (No. 12-1339).

172. *Id.* at 8 (quoting *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 615 (2011)).

173. See *supra* Part II.A.1.b.

174. Brief of Pharm. Research & Mfrs. of Am. (PhRMA) as Amicus Curiae in Support of Respondent, *supra* note 108, at 4. According to PhRMA, *Chevron* deference was not warranted because an interpretation announced in an amicus brief does not go through notice and comment rulemaking. And *Auer* deference was not warranted because the regulation merely parrots the statute. *Id.* at 28.

175. Brief for Pharm. Research & Mfrs. of Am. as Amicus Curiae in Support of Petitioner, *supra* note 171, at 9.

176. Press Release, Wash. Legal Found., WLF Hails FDA Policy Statement on Preemption of Failure-to-Warn Suits (Jan. 25, 2006), <http://www.wlf.org/upload/012506RS.pdf> [<https://perma.cc/V7X7-B7DY>].

FDA policy cannot be sued under state law for failure to include additional safety warnings in their product labeling.”<sup>177</sup> According to then-WLF Chief Counsel Richard Samp, “[t]he policy statement does not represent a shift in FDA’s views; FDA has taken the same position in litigation for several years. Nonetheless, issuing the policy statement is an important step, because it significantly increases the likelihood that courts will heed FDA’s views.”<sup>178</sup> WLF noted that “because views expressed in the course of litigation are not deemed official positions of a federal agency courts [had not been] required to defer to FDA’s views.”<sup>179</sup> But “WLF argued that because those views have been incorporated into an official policy statement, courts are now required to give deference to FDA’s interpretation of federal law.”<sup>180</sup> Accordingly, in its amicus brief in *Wyeth*, WLF took the position that the “FDA’s view that the imposition of liability under state law for defendant’s alleged failure to warn *would* interfere with FDA’s accomplishment of regulatory objectives is in our view entitled to at least as much deference, if not more, as the FDA’s view of its preemption authority.”<sup>181</sup>

WLF’s position here contradicts its emphatic endorsement—three years later in *Christopher*—of the *Wyeth* Court’s ultimate refusal to give deference to the FDA’s interpretation of the scope of its own preemption authority. Indeed, its amicus brief cited with approval the Court’s refusal in *Wyeth* to give deference to the FDA’s interpretation of the scope of its own preemption authority in light of the FDA’s “procedural failure” in failing to give an opportunity for notice and comment, and advocated that “[t]he same result should obtain here.”<sup>182</sup> It also echoed Justice Scalia’s warning in *Talk America* that “allowing an agency to both promulgate its own rules as well as interpret them ‘frustrates the notice and predictability purposes of rulemaking, and promotes arbitrary government.’”<sup>183</sup>

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177. *Id.* at 1.

178. *Id.*

179. *Id.* at 2.

180. *Id.*

181. Brief of Wash. Legal Found. & Am. Coll. of Emergency Physicians as Amici Curiae in Support of Petitioner at 13, *Wyeth v. Levine*, 555 U.S. 555 (2008) (No. 06-1249) (quoting *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 275 (3d Cir. 2008), *vacated*, 129 S. Ct. 1578 (2009)).

182. Brief of Wash. Legal Found. et al. as Amici Curiae in Support of Respondent, *supra* note 103, at 16 (quoting *Wyeth*, 555 U.S. at 577).

183. *Id.* at 10–11 (quoting *Talk Am., Inc. v. Mich. Bell Tel. Co.*, 564 U.S. 50, 69 (2011) (Scalia, J., concurring)). To be sure, WLF did not take a categorically anti-*Auer* position in *Christopher*. It acknowledged that “[u]nder *Auer*, an agency’s interpretation of an ambiguous regulation is sometimes entitled to deference because it is presumed that the agency is best situated to interpret its own words.” *Id.* at 18. But it made clear that “an agency cannot properly

Even the Chamber of Commerce, otherwise so scrupulously consistent in opposing *Auer* deference, has wavered in this line of cases. In *Riegel*, the Chamber argued that the MDA preempted requirements imposed by state tort law. For support, it cited the brief submitted by the Solicitor General at the petition stage, noting that “the FDA interprets Section 360k(a) as expressly preempting state tort claims that seek to impose different or additional requirements on devices that have won premarket approval.”<sup>184</sup> The Chamber also cites additional statements made by the FDA as amicus in another device preemption case, noting that the “FDA recognizes that the MDA’s express preemption clause furthers not only Congress’s goal of protecting innovation and reducing regulatory burdens but also its goal of protecting and promoting the public health.”<sup>185</sup>

In *Wyeth*, the Chamber criticized the Vermont Supreme Court, which had ruled against *Wyeth* below, for “declin[ing] to give any weight to certain statements made by the FDA relating to preemption and the adverse and disruptive effects of certain state-law product liability lawsuits on the federal regulatory scheme.”<sup>186</sup> In doing so, the Chamber explicitly invoked *Auer* deference. According to the Chamber, the lower court’s interpretation of a key FDA regulation ran counter to the FDA’s own interpretation of the provision.<sup>187</sup> Moreover, the Chamber, citing *Auer*, asserted that the “FDA’s longstanding interpretation of the CBE regulation is entitled to deference under settled principles of administrative law.”<sup>188</sup>

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claim to be ‘interpreting’ a regulation when it is in effect *changing* that regulation.” *Id.*

184. Brief of the Chamber of Commerce of the U.S. as Amicus Curiae in Support of Respondent, *supra* note 18, at 6.

185. *Id.* at 7.

186. Brief of the Chamber of Commerce of the U.S. as Amicus Curiae in Support of Petitioner at 7–8, *Wyeth v. Levine*, 555 U.S. 555 (2009) (No. 06-1249). The Chamber also took the lower court to task for its reliance on the “presumption against preemption.” *Id.* at 7.

187. *Id.* at 10–11 (explaining that the lower court “incorrectly thought that Section 314.70 [the “Changes Being Effected” provision of the FDA’s labeling regulations] allowed *Wyeth* to make unilateral changes to [Phenergan’s] drug label[ ] without obtaining prior FDA approval whenever [Wyeth] believes it will make the product safer,” when “[i]n fact, the FDA has long interpreted the CBE regulation as permitting changes to labeling only where the changes reflect *newly discovered information* about the drug’s safety—information that the FDA has not previously considered.” (internal quotation marks omitted)).

188. *Id.* at 11 (citing *Auer v. Robbins*, 519 U.S. 452, 461 (1997)). The Chamber also implicitly endorsed *Chevron* deference by urging that “courts should apply the ordinary rules relating to deference to administrative agencies’ interpretations of the statutes and regulations they administer at this first step of the [conflict preemption] analysis,” in which the court interprets the relevant

*b. Preemption Reconsidered*

We return to the puzzle in *PLIVA*; namely, Justice Thomas' curious invocation of *Auer* deference to sustain the pro-preemption holding. The Chamber did not participate as an amicus in *PLIVA*,<sup>189</sup> so in this case, the Court did not seem to be following the Chamber's urging.

Petitioners *PLIVA* and *Actavis* each addressed *Auer* deference. *PLIVA* reminded the Court that the FDA "interpreted the CBE provision to . . . preclude deviations between the branded and generic product labeling."<sup>190</sup> And, *PLIVA* contended, the "FDA's settled interpretation of its own regulations is entitled to substantial deference[,] . . . the virtually conclusive deference to which it is due" under *Auer*.<sup>191</sup> The *Actavis* brief echoed the deference arguments made by *PLIVA*. It also argued that the FDA's "regulations preempt state failure-to-warn claims which would require a generic manufacturer to unilaterally change its label" and even if "there were any ambiguity in the Agency's

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federal and state laws. *Id.* at 30. Specifically, with respect to implied preemption analysis, the Chamber argued that when a court evaluates "the extent of the conflict between state and federal laws and . . . determin[es] whether the inconsistency rises to the level of a violation of the Supremacy Clause," it is "entirely appropriate to afford substantial weight to the views of an administrative agency charged with implementing a comprehensive regulatory scheme in a technical area where, as here, the agency concludes, for persuasive reasons, that state regulation interferes with its regulatory regime or presents an obstacle to the achievement of federal objectives." *Id.* at 30–31 (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996); *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 883 (2000)). According to the Chamber, this "approach makes eminent sense" because "[t]he determination whether state law stands as an obstacle to a complex federal regulatory scheme often . . . involve[s] technical or policy-based judgments about the practical effect of state law on the efficient and effective operation of a complex statutory and regulatory scheme—judgments that an administrative agency such as the FDA is uniquely well suited to make." *Id.* at 31–32. Thus, the Chamber argues, "the Court should also give substantial weight to the FDA's 2006 statements [in the preamble to its drug labeling rule] relating to preemption and the adverse and disruptive effects of certain state-law product liability lawsuits on the federal regulatory scheme," which are "persuasive and thus deserving of substantial weight in this Court." *Id.* at 11.

189. A likely explanation is that its members were divided on the issue—namely whether generic drug manufacturers should be shielded from liability by preemption whereas brand name manufacturers were not (in light of *Wyeth*).

190. Brief of Petitioners *PLIVA, Inc.*; *TEVA Pharm. USA Inc. & UDL Labs, Inc.* at 43, *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) (Nos. 09-993, 09-1039, 09-1501).

191. *Id.*

regulations, . . . then the Agency’s consistent and longstanding interpretation of those regulations would be entitled to deference” under *Auer*.<sup>192</sup>

Nonetheless, as PLIVA pointed out in its brief, the FDA regulation at 21 C.F.R. § 314.3(b) explicitly stated that the duty of sameness applied not only to the manufacturer’s initial label application to the FDA but also to “*all* amendments and supplements.”<sup>193</sup> Justice Thomas could have opted to hold that this regulation was unambiguous on its face, thereby reaching the same conclusion without resorting to *Auer*.

In *Mutual Pharmaceutical*, there was nary a mention of *Auer*, nor did any of the parties or other amici briefs invoke *Auer*. A joint amicus brief submitted by the Chamber and PhRMA, consistent with their prior amicus briefs in preemption cases, emphasized the comparative advantage of drug labeling regulation by the expert FDA over lay jurors. Thus, they argued that “FDA’s risk-benefit analyses should be favored because they are objectively better in promoting public health than equivalent determinations by votes of lay jurors” and because the “FDA relies on its experienced staff and panels of trained medical and pharmacological experts[, whereas] there is no suggestion that the lay jury in New Hampshire had the benefit of such expertise.”<sup>194</sup> Moreover, they argued, “FDA review of a[] [New Drug Application] typically includes a year or more of close analysis; a jury trial may take a few days or weeks” and the “FDA must balance the benefits of the proposed drug to the entire treatable population against the potential incidence of its known risks” whereas “however instructed, a jury’s attention cannot help but be focused on a single, grievously injured individual.”<sup>195</sup>

### CONCLUSION: WHAT THE FUTURE HOLDS

The business community’s uniting in opposition to *Auer* deference is proceeding apace. In a recent case, *Bible v. United Student Aid Funds, Inc.*,<sup>196</sup> business groups joined forces in an all-out assault on *Auer* deference. The National Association of Manufacturers (“NAM”) urged the

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192. Brief of Petitioners Actavis Inc. & Actavis Elizabeth LLC at 22, *Mensing*, 564 U.S. 604 (Nos. 09-993, 09-1039,09-1501).

193. Brief of Petitioners PLIVA, Inc.; TEVA Pharms. USA Inc. & UDL Labs, Inc., *supra* note 190, at 33.

194. Brief of the Chamber of Commerce of the U.S. of Am. & Pharm. Research & Mfrs. of Am. as Amici Curiae in Support of Petitioner, *supra* note 12, at 20.

195. *Id.*

196. 799 F.3d 633 (7th Cir. 2015), *cert. denied*, 136 S. Ct. 1607 (2016). The *Bible* case involved the question whether a borrower’s state-law breach of contract claim against a guaranty agency for her student loans is preempted by the Higher Education Act (HEA). The Seventh Circuit Court of Appeals held that the claim was not preempted by the HEA because it did not conflict with



U.S. Supreme Court to take the case given that “[t]his case presents an ideal opportunity to overrule the deferential perspectives mandated by *Auer* . . . and . . . *Seminole Rock*.”<sup>197</sup> It noted the “[s]erious concerns regarding *Auer* and *Seminole Rock* deference [that] have been voiced by the Chief Justice and other members of this Court” and raised the specter of “the danger posed by the growing power of the administrative state.”<sup>198</sup> WLF joined groups like NAM<sup>199</sup> in calling for *Auer* deference to be “reject[ed] . . . once and for all.”<sup>200</sup> WLF warned ominously that “if the Court allows the rule of deference announced in *Auer* . . . [and]

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federal law and opined that the contract at issue “simply incorporate[d] applicable federal regulations as the standard for compliance.” *Id.* at 639. In so holding, the court deferred to the Secretary of Education’s interpretations of the applicable statutes and regulations as providing that “a guaranty agency may not impose collection costs on a borrower who is in default for the first time but who has timely entered into and complied with an alternative repayment agreement.” *Id.*

197. Brief of Nat’l Ass’n of Mfrs. & the Nat’l Shooting Sports Found., Inc. as Amici Curiae in Support of Petitioners at 2, *Bible*, 799 F.3d 633 (No. 15-861).
198. *Id.* at 3 (quoting *City of Arlington v. Fed. Commc’ns Comm’n*, 133 S. Ct. 1863, 1879 (2013) (Roberts, C.J., dissenting)). The brief cited all of the Justices’ opinions expressing reservations about *Auer* from *City of Arlington*, *Decker*, and *Perez*. NAM explained that “*Amici* are concerned that such deference may actually provide *disincentives* for regulatory clarity, thereby sacrificing notice and predictability in rulemaking,” and suggested that *Auer* “might be understood as an end-run around rulemaking in the extreme.” *Id.* at 4–5 (quoting Lisa Schultz Bressman, *Beyond Accountability: Arbitrariness and Legitimacy in the Administrative State*, 78 N.Y.U. L. REV. 461, 552 (2003)). NAM insisted that *Auer* conflicts with the APA, which “allocates interpretive authority to the judiciary,” and threatens separation of powers. *Id.* at 8–13. NAM took particular issue with agency interpretations announced in an amicus brief during litigation, outside of the context of rulemaking, as was true in the case at hand. *Id.* at 13–14.
199. Nor has NAM been steadfast in its resistance to *Auer*. Consider, for example, its amicus brief in *In re Polar Bear Endangered Species Act Listing & 4(d) Rule Litig.*, 794 F. Supp. 2d 65 (D.D.C. 2011). NAM argued that the Fish and Wildlife Service’s “preambles and documents interpret[ing]” the Endangered Species Act rules “are entitled to deference” under *Auer*. Memorandum of the Nat’l Trade Ass’ns in Opposition to Plaintiffs’ Motion for Summary Judgment on the 4(d) Rule & in Support of Fed. Defendants’ Cross-Motion for Summary Judgment on the 4(d) Rule at 14, *In re Polar Bear Endangered Species Act Listing & 4(d) Rule Litig.*, 794 F. Supp. 2d 65 (Nos. 1:08-cv-2113, 1:09-cv-0159). More generally, NAM argued that on “science issues, judicial review must generally be at its most deferential” because “a federal agency must have discretion to rely on the reasonable opinions of its own qualified experts even if the court might find contrary views more persuasive.” *Id.* (internal citations and quotation marks omitted).
200. Brief of Professor Philip Hamburger & Wash. Legal Found., as Amici Curiae in Support of Petitioner at 2, *Bible*, 799 F.3d 633 (No. 15-861).

*Seminole Rock* . . . to stand, it will sanction a profound and ongoing injustice that damages its reputation.”<sup>201</sup>

But the *Bible* case was litigated and decided in the era of President Obama. Will the business community need to rally for *Auer*'s demise in what promises to be an era of minimal regulation under the Trump Administration? In the wake of President Trump's early initiatives signaling regulatory rollback, the NFIB has predicted that “[f]or small businesses, 2017 may end up being the year the regulatory tide turn[s].”<sup>202</sup> More specifically, the NFIB characterized Executive Order 13771,<sup>203</sup> in conjunction with the regulatory freeze ordered by White House Chief of Staff Reince Priebus on January 20, 2017, as “a very lethal weapon against regulatory overreach.”<sup>204</sup> In a similar vein, the Chamber has pronounced that “[a]fter years of talk, Washington is actually starting to tame the regulatory leviathan.”<sup>205</sup> If the President himself has expressed wariness of “a system that no longer imposes any

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201. *Id.* The brief articulated two primary arguments for renouncing *Auer*. First, it argued that *Auer* deference “requires Article III judges to abandon their office and duty of independent judgment” under the Constitution. *Id.* at 3. Second, it argued that because “*Auer* precommits judges to favor one party over another” where one of those parties is a federal agency, it “requires judges to adopt a systematic bias in favor of the government” that violates the Fifth Amendment’s guarantee of due process of law. *Id.* at 4.

202. *President Trump Is Pushing Regulations out the Door*, NAT’L FED’N OF INDEP. BUS. (Feb. 1, 2017), <http://www.nfib.com/content/analysis/national/donald-trump-is-pushing-regulations-out-the-door/> [<https://perma.cc/K3NW-DRWR>].

203. Exec. Order No. 13771, 82 Fed. Reg. 9339 (Feb. 3, 2017).

204. *Id.* On the day that President Trump announced Executive Order 13771, the NFIB issued a press release: “[t]he President’s order is a good first step on the long road toward eliminating ball-and-chain regulations so small businesses can create jobs and expand the economy.” *NFIB Welcomes Trump’s Actions on Regulations*, NAT’L FED’N OF INDEP. BUS. (Jan. 30, 2017), <http://www.nfib.com/content/press-release/economy/nfib-welcomes-trumps-actions-on-regulations/> [<https://perma.cc/7GM6-W2X4>]. The statement urged regulatory agencies and the Office of Management and Budget to “keep . . . in mind” that “the extraordinary costs and complexity of regulations falls hardest on America’s small and independent businesses.” *Id.*

205. Sean Hackbarth, *How Congress and Trump Are Taming the Regulatory Leviathan*, U.S. CHAMBER OF COMMERCE (Feb. 14, 2017, 5:15 PM), <https://www.uschamber.com/above-the-fold/how-congress-and-trump-are-taming-the-regulatory-leviathan> [<https://perma.cc/5LTB-HMJY>]. Unlike NFIB, the Chamber did not immediately issue a statement regarding Executive Order 13771, but two weeks later, its senior vice president and chief policy officer said in an interview that it is not the two-for-one provision, but rather the provision requiring the net cost of all new regulations to be zero that “really can have a profound impact. It gives you a new target for when you’re writing regulations.” Juliet Eilperin, *Why Trump’s Order to Cut Government Regulation Is Even Bolder Than It Seems*, WASH. POST. (Feb. 13, 2017), <https://www.washingtonpost.com/news/powerpost/wp/2017/02/13/why-trumps->

meaningful checks on executive action,”<sup>206</sup> and has nominated agency heads who enthusiastically share his views, need the business community fear overzealous agency action or expansive interpretations of agency power?

Alternatively, should the steadfast resistance to *Auer* deference hold, what would that mean in the preemption context? If *Auer* deference is no longer a reliable pillar of preemption in the generic drug preemption context (and beyond), business groups might switch gears with an increased emphasis on lobbying affected agencies for preemptive rulemaking as well as increased efforts lobbying Congress for express preemption provisions.<sup>207</sup>

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order-to-cut-government-regulation-is-even-bolder-than-it-seems/ [https://perma.cc/6ZZN-4799].

206. Brief of Amici Curiae Se. Legal Found., Nat’l Fed’n of Indep. Bus. Small Bus. Legal Ctr., The Buckeye Inst., The Beacon Ctr. of Tenn. & Thomas P. Gross in Support of Petitioner, *supra* note 135 at 5.

207. Business groups have already turned their attention to Congress with respect to reining in the regulatory state. The Chamber’s website notes that “now is the time to seriously think about how federal regulations get made,” insisting that “[w]hile the Constitution requires a lot of effort to write a new law, over the decades it’s become relatively easy for federal agencies to write regulations that have the full weight of law,” to which “federal courts have given . . . tremendous deference.” Hackbarth, *supra* note 205. As a solution, the Chamber proposes the Regulatory Accountability Act, which recently passed the House vote and will soon be before the Senate. *Id.*; Letter from 616 Bus. Grps. & Ass’ns to Mitch McConnell and Charles Schumer, Senate Majority Leader and Democratic Leader (Feb. 6, 2017), [https://www.uschamber.com/sites/default/files/documents/files/2.6.17-\\_multi-association\\_letter\\_to\\_senate\\_supporting\\_the\\_regulatory\\_accountability\\_act.pdf](https://www.uschamber.com/sites/default/files/documents/files/2.6.17-_multi-association_letter_to_senate_supporting_the_regulatory_accountability_act.pdf) [https://perma.cc/F557-KESB]. Significantly, the Regulatory Accountability Act bill—which includes the Separation of Powers Restoration Act—amends 5 U.S.C. § 706 to eliminate judicial deference to an agency’s determination of the costs and benefits or other economic or risk assessment if the agency failed to conform to guidelines established by OIRA, determinations made in the adoption of an interim rule, or guidance. *See* Regulatory Accountability Act of 2017, H.R. 5, 115th Cong. sec. 107, § 706. It is thus not a stretch to imagine such groups urging Congress to intervene in the federal preemption context as well. And this approach, moreover, would obviate the need to rely on deference to federal agencies in that context.