

# Tort-Agency Partnerships in an Age of Preemption

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*At the core of the tort preemption cases before the U.S. Supreme Court is the extent to which state law can impose more stringent liability standards than federal law. The express preemption cases focus on whether the state law requirements are “different from, or in addition to” the federally imposed requirements. And the implied conflict preemption cases examine whether the state law standards are incompatible (impossibility preemption) or at least at odds (obstacle preemption) with the federal regulatory scheme.*

*But the preemption cases in the appellate pipeline — what I shall term the “second wave” of preemption cases — address a separate analytic question. Their focus is less on the substantive aspects of regulatory standards, and more on their enforcement. When can state tort law impose substantive duties or obligations that are “parallel” to federal requirements without thereby encroaching upon a federal agency’s discretionary enforcement prerogative? This is the new frontier in products liability preemption.*

*My proposed model suggests that courts facing these new issues should solicit input from federal agencies before resolving them. The model thereby offers a hybrid private-public model for the regulation of health and safety. It advocates an extension of my “agency reference model” to the “enforcement preemption” context: courts should place more emphasis on FDA input when deciding whether tort requirements are “parallel” to federal dictates, and (perhaps even*

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*more so) whether, even if they are, they nonetheless infringe on the federal agency's discretionary enforcement prerogatives. Courts would thus seek guidance from federal agencies to determine whether a private right of action exists for the enforcement, via state law claims, of federal regulations.*

## INTRODUCTION

Federal preemption of state tort law can hamper the promotion of health and safety. Tort preemption decisions rendered by the U.S. Supreme Court over the last two decades seem to triumph industry interests over consumer and patient interests. But ironically, it is here, in the shadow of preemption, that the opportunity exists to create new tort-agency partnerships to regulate health and safety. The key lies in the ubiquitous “parallel requirements” exception to preemption: namely, that preemption does not occur where state tort law *complements* the federal regulatory regime.

The issue of when state tort law's substantive duties or obligations are indeed “parallel” to federal requirements and not an encroachment on a federal agency's discretionary enforcement powers is the new frontier in products liability preemption. This new tort-agency joint enterprise to promote health and safety raises many questions. To what extent should state and federal courts have free rein to question federal agency decision-making processes? Are courts equipped to decide whether, and to what extent, state tort law claims complement federal regulatory schemes? Are agencies?

To date, the core issue in the tort preemption cases before the Supreme Court has been the extent to which state law can impose more stringent substantive liability standards than federal law in the specific areas in which Congress has legislated (e.g., medical devices and drugs, automobiles, pesticides).<sup>1</sup> The express preemption cases focus on whether state law imposes requirements that are “different from, or in addition to” the federally imposed requirements.<sup>2</sup> And the implied conflict preemption cases look to whether the state law standards are either incompatible with the federal dictates (impossibility preemption) or

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1 Under the U.S. Constitution's Supremacy Clause, state law causes of action may be barred by federal law, which is “the supreme law of the land . . . anything in the . . . laws of any state to the contrary notwithstanding.” U.S. CONST. art. VI, cl. 2.

2 Express preemption occurs where Congress's intent to displace state law is explicit in the language of the federal statute.

else are in some degree of tension with their ultimate purposes or objectives (obstacle preemption).<sup>3</sup>

In terms of regulatory policy, two fundamental questions emerge from these cases. The first question is whether a federal regulatory standard is a “minimum” health and safety standard or instead an “optimal” one. To the extent that the substantive federal standard is a minimum, then state law should be able to impose a heightened standard. However, to the extent that it is an optimal one — based on a comprehensive cost-benefit analysis, taking into account the inherent tradeoffs at different levels of stringency — then the imposition of additional state law requirements is counterproductive, leading to costly over-deterrence.

The second question is whether to regulate at the national or the state level. Regulation at the state level facilitates experimentation among different approaches and levels of stringency; state-level regulation also allows for a closer fit between regulatory goals and preferences of more localized populations. For example, if citizens of a particular state value safety at greater cost in terms of restricted products, a balance could be struck with state law imposing heightened safety standards. But there is a cost to such decentralized regulation, especially when it comes to regulating products for a national (and increasingly international) market. There are efficiency gains in terms of economies of scope and scale in producing uniform goods for a mass market. Moreover, state regulation can export costs onto other states; states can, for example, secure the benefits of more stringent requirements in terms of greater safety, while foisting some portion of the costs onto other states.<sup>4</sup> Conversely, states might under-regulate — for example, in terms of environmental standards — in situations where they are able to capture the benefits (attracting industry into the state, which brings additional jobs and revenue into the state) while exporting the costs (pollution to downstream states). Collective action problems are one such externality that calls for a solution at the national level.<sup>5</sup>

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3 Implied preemption is divided into “field” and “conflict” preemption, where courts must determine Congress’s intent from a statute that is silent on the issue of preemption. The conflict preemption approach dominates judicial treatment of preemption of state tort law, with its attendant focus on whether state tort law claims are in tension with the federal regulatory regime.

4 For a discussion of the externalities argument in favor of national regulation of products, see Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 UCLA L. REV. 1353 (2006); see also Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449 (2008) [hereinafter Sharkey, *Products Liability Preemption*].

5 See, e.g., Robert D. Cooter & Neil S. Siegel, *Collective Action Federalism: A*

What I shall term the “second wave” of preemption cases addresses a separate analytic question, turning from a focus on the setting of *substantive* standards to the *enforcement* of such standards. Preemption in this context would amount to what has been termed field preemption — namely, the federal regulatory scheme is so comprehensive as to leave no room for state law involvement, whether in the setting or enforcement of substantive standards. Field preemption displaces not only competing state regulatory standards, but remedies for violation of federal standards as well. Field preemption is not common in the products liability realm. State law has historically defined health and safety standards. Moreover, whereas concerns regarding state exportation of costs in terms of externalities and collective action problems are rife with respect to a state’s setting of more stringent substantive liability standards, such concerns are attenuated in the context of state enforcement of uniform federal standards.<sup>6</sup>

This Article examines the intersection of state private tort law and federal public agencies. Part I looks at the “parallel requirements” exception to federal preemption and the key cases in this area. Part II addresses the extent to which plaintiffs may assert state-law claims for violations of federal law, at the risk of encroaching on agencies’ own authority to enforce the federal regulatory regime. Finally, Part III explores possibilities for tort-agency partnerships, in particular the use of agency input in judicial decision-making. My proposed model suggests that courts should solicit input from agencies and thereby offers a hybrid private-public model for the regulation of health and safety: the range of state law enforcement avenues for private plaintiffs should be decided in consideration of the agency’s position on preemption.

## I. PARALLEL REQUIREMENTS

Recent U.S. Supreme Court decisions undoubtedly, and significantly, constrict the scope of state-law tort claims for allegedly defective FDA-approved medical

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*General Theory of Article I, Section 8*, 63 STAN. L. REV. 115 (2010) (providing a theory to explain Congress’s Article I, section 8 powers as a solution to externalities, free riding, and hold-out problems that arise when states act individually). According to Cooter and Siegel, power should be assigned to the smallest unit of government that internalizes the effects of its exercise.

6 Specifically, a product manufacturer must comply with the same, uniform national regulations regardless of the state enforcement action; thus it is less likely that the effects of state enforcement actions would be externalized to other states. See Cooter & Siegel, *supra* note 5.

devices and generic drugs that can survive federal preemption.<sup>7</sup> However, the specter of preemption has redirected plaintiffs (and their attorneys) to bring “parallel requirements” cases. Private plaintiffs can generally pursue state tort claims enforcing state requirements that are “parallel” to federal statutory schemes. These claims survive dismissal motions based on express preemption — where typically Congress prohibits state-law requirements that are not identical (or are “in addition to or different from”) federal standards. Plaintiffs’ claims likewise withstand dismissals based on implied conflict preemption, where Congress has remained silent, but nonetheless courts scrutinize whether the state tort law poses either an irreconcilable (impossibility preemption) or formidable (obstacle preemption) tension with the federal regulatory scheme.

Thus, in the shadow of preemption, a new (or resurrected) species of tort claims has arisen. I explore this new breed of causes of action, taking up, in turn, common law and statutory actions — defined, in essence, by their viability in the face of preemption.

### A. Common Law Actions

Common law negligence per se actions — where the violation of a statute or regulation constitutes breach of a duty of reasonable care — are exemplars of “parallel requirements” claims.<sup>8</sup> By definition, state-law duties that incorporate

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7 It was via express preemption that *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), wiped out state tort claims arising from design defects in medical devices. Those claims were deemed untenable in the face of the federal Medical Device Amendments of 1976 (MDA) to the Food, Drug, and Cosmetic Act (FDCA), which prohibits state-law common law actions that impose requirements for additional warnings or safety features on FDA-approved medical devices “different from or in addition to” the federal requirements. Medical Devices Amendments of 1976, Pub. L. 94-295, 90 Stat. 539 (codified at 21 U.S.C. § 360k(a) (2012)). *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), similarly wiped out state tort claims alleging failure to warn and design defect of the dangers of FDA-approved generic pharmaceutical drugs, respectively. Implied conflict preemption was the means to this end; namely, given that a generic drug manufacturer cannot unilaterally (i.e., on its own, without prior FDA approval) change its label, it would be impossible for it to comply simultaneously with a state-law dictate to amend its label and the FDA regulatory command that its label be the “same” as that of its brand-name counterpart.

8 Negligence per se enables plaintiffs to establish as a matter of law that the defendant’s conduct constituted a breach of duty in a negligence action, so that only causation and damages need be proved.

the violation of a federal statute “parallel” rather than add to, or conflict with, the federal requirement. Negligence per se may establish the appropriate standard of care for the tort, but the doctrine may *not* be used to create an independent basis of tort liability. In other words, the doctrine establishes, by reference to a statutory scheme, the standard of care appropriate to the underlying tort; it does not create an independent basis of tort liability. So long as authorized by state law, negligence per se lawsuits should survive even the most vigorous express preemption challenges.<sup>9</sup>

### *I. “Failure to Update” Torts*

A new breed of state-law torts, hoping to capitalize on the “parallel requirement” exception to preemption, has emerged in the medical device and drug arenas: state-law failure-to-warn cases premised upon breach of federal duties. Plaintiffs assert these claims against device manufacturers who failed to report adverse events to the FDA and against generic drug manufacturers who failed to update drug labels to comport with revisions to brand-name drug labels.

#### *i. Medical Devices*

The Medical Devices Amendment (MDA) to the Food, Drug and Cosmetic Act (FDCA) requires medical device manufacturers to report information to the FDA even after a device’s market approval. Manufacturers, for example, must submit adverse-event reports to the FDA whenever the manufacturer becomes aware that one of its devices has malfunctioned in a way that would likely lead to serious injury or death.<sup>10</sup>

A recent high profile case from the Ninth Circuit (sitting en banc), *Stengel v. Medtronic, Inc.*, illustrates the emergent category of medical device “parallel

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9 There is no federal private right of action under the FDCA. 21 U.S.C. § 337(a) (2012); *see also* *Merrill Dow Pharms., Inc. v. Thompson*, 478 U.S. 804, 811 (1986). In the majority of jurisdictions in the United States, the lack of a statutory private right of action does not preclude state law negligence per se actions. *See, e.g.*, RICHARD A. EPSTEIN & CATHERINE M. SHARKEY, *CASES AND MATERIALS ON TORTS* 246-47 (10th ed. 2012) (discussing the majority and minority positions on negligence per se actions). The Supreme Court has not ruled directly on the question whether state-law negligence per se actions are restricted under the FDCA. Lower federal and state courts are split on the issue. *See* 1 CHARLES S. ZIMMERMAN, *PHARMACEUTICAL AND MEDICAL DEVICE LITIGATION* § 15A.22 (2013) (citing cases in both camps).

10 *See* 21 U.S.C. § 360e(b)(1)(B) (2012).

requirements” cases.<sup>11</sup> Plaintiffs alleged that Medtronic was negligent under Arizona law because it failed to provide the FDA with information about adverse events involving one of its medical devices.<sup>12</sup> The Ninth Circuit held that this state-law claim was neither expressly nor impliedly preempted by the MDA.<sup>13</sup> In so holding, the court held that the general duty of care under Arizona common law incorporated a requirement to furnish adverse-event information to the FDA.<sup>14</sup>

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- 11 *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013); *accord Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769 (5th Cir. 2011) (“[A] failure to warn claim limited to an assertion that the defendant violated a relevant federal statute or regulation is ‘parallel’ to federal requirements as defined in *Riegel*.”); *Bausch v. Stryker Co.*, 630 F.3d 546, 557-58 (7th Cir. 2010) (holding that “parallel” state-law strict liability and negligence claims were not expressly preempted by the MDA, or impliedly preempted by *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001)). *But see Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2006) (holding negligence per se claim preempted in a case involving a manufacturer of defective pacemaker leads).
  - 12 In an amended complaint, plaintiffs alleged that Medtronic had “a continuing duty to . . . report to the FDA any complaints about the product’s performance and any adverse health consequences of which it became aware and that are or may be attributable to the product.” *Stengel*, 704 F.3d at 1232.
  - 13 *See id.* at 1233 (“[W]e . . . hold, under [*Medtronic v. Lohr*, 518 U.S. 470 (1996)], *Buckman*, and *Riegel*, that this claim is not preempted, either expressly or impliedly, by the MDA.”). The Ninth Circuit thus “join[ed] the Fifth and Seventh Circuits, which reached the same conclusion with respect to comparable state-law claims in *Hughes* and *Bausch*.” *Id.* *Lohr* and *Riegel* address the “parallel requirements” exception to express preemption. *Buckman* implied preemption is discussed further below in Part II.
  - 14 *Id.* at 1235. Medtronic has sought review by the U.S. Supreme Court, where there is a pending decision on whether to grant certiorari. *See* Petition for Writ of Certiorari for Defendant-Appellant, *Medtronic, Inc. v. Stengel* (No. 12-1351) (May 10, 2013). On October 7, 2013, the U.S. Supreme Court called for the views of the Solicitor General, which filed its response on May 20, 2014. Urging the Court to deny the certiorari petition, the Solicitor General suggested that the “subtle question of parallelism” could be avoided if the state law failure-to-warn claim were framed properly as stemming from the manufacturer’s failure to make a revision to the device’s labeling to strengthen the warning based on “new safety information.” Brief for the United States as Amicus Curiae at 14, 13, *Stengel* (No. 12-1351). The Solicitor General raised a novel argument that such a failure-to-warn claim falls outside the scope of the MDA’s express preemption provision because it does not implicate a “device-specific federal requirement.” *See id.* at 15 (“The courts of appeals, in every case since *Riegel* involving a device subject to premarket approval, have tacitly dispensed with

## ii. Pharmaceuticals

An analogous breed of state-law tort claims against generic drug manufacturers has emerged in the wake of the Supreme Court's generic preemption cases, *Mensing* and *Bartlett*.<sup>15</sup> The relevant federal duty in this context is a generic drug manufacturer's "duty of sameness" to ensure that its labeling matches the brand-name manufacturer's.<sup>16</sup> State law claims premised on the failure of a generic drug manufacturer to update its warning to match that of the brand-name's newly revised label capitalize on this narrow federal duty, without expanding the state law duties beyond it. Indeed, these cases can be viewed as affirmative efforts on plaintiffs' part to enforce "parallel requirements."<sup>17</sup>

The Sixth Circuit addressed such a claim in *Fulgenzi v. PLIVA, Inc.*<sup>18</sup> The FDA had approved a labeling change for a brand-name drug. The generic manufacturer failed to update its warning to match the brand-name counterpart and further failed to communicate the brand-name label's change to physicians.<sup>19</sup> Given that the generic could have changed its label to match the brand-name — and indeed, it had a federal duty to do so — the Sixth Circuit determined that the case fell outside of the *Mensing* impossibility preemption parameters.<sup>20</sup> The court also rejected obstacle preemption, holding that "state laws that

the first step of a proper Section 360k(a) preemption analysis — i.e., asking whether FDA has established device-specific requirements on the same subject as the relevant state requirement.”).

15 *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011); *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

16 *See, e.g., Mensing*, 131 S. Ct. at 2574 (“A manufacturer seeking generic drug approval . . . is responsible for ensuring that its warning label is the same as the brand name’s.”).

17 A related (albeit generally unsuccessful) species of claim after *Mensing* is the “failure to communicate” tort, where plaintiffs concede that the labeling is adequate, but allege that the manufacturer has failed to inform medical providers and to make consumers aware of a labeling change. *See, e.g., Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013) (holding that the failure-to-communicate theory was untenable “[b]ecause the duty of sameness prohibits the generic manufacturers from taking such action unilaterally, they are dependent on brand-names taking the lead”) (quoting *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013)).

18 *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013); *see also Fisher v. Pelstring*, 817 F. Supp. 2d 791 (D.S.C. 2011) (holding that generic’s failure to match the new FDA-approved warning for branded drugs not preempted under *Mensing* because it was possible for the generic to update its labels to match that of its brand-name counterpart).

19 *Fulgenzi*, 711 F.3d at 580.

20 *Id.* at 584-85.



provide damages for inadequate warnings in violation of the federal duty of sameness do not conflict with federal drug policy, with respect to purposes-and-objectives preemption.”<sup>21</sup>

This type of “failure to update” tort action is narrower than the version pressed by the U.S. Government, representing the FDA, in the *Mensing* case. The Government argued that all drug manufacturers (including generics) have a duty to revise warnings “as soon as there is reasonable evidence of an association of a serious hazard with a drug.”<sup>22</sup> According to the Government, generic manufacturers thus have a federal “duty to update” the FDA — and state-law tort claims premised on breach of this duty should not be preempted.<sup>23</sup>

The U.S. Supreme Court in *Mensing* was skeptical of such a state-law claim premised upon a federal “duty to update” the FDA. As the Court construed the state law duty, “Although requesting FDA assistance would have satisfied the Manufacturers’ federal duty, it would not have satisfied their state tort-law duty to provide adequate labeling. State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label.”<sup>24</sup> Indeed, the Court concluded that the plaintiffs themselves denied that their state-law claims were based on the manufacturer’s alleged failure to update the FDA.<sup>25</sup> The Court thus held the state law claims preempted.

## 2. “Misbranding” Torts

The U.S. Government, again representing the FDA, had a second chance to define a viable state-law tort claim in the wake of *Mensing*. *Mutual Pharmaceutical Co. v. Bartlett*<sup>26</sup> raised the question whether a design defect claim (as opposed to a failure-to-warn claim, as was at issue in *Mensing*) against a generic manufacturer is preempted.

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21 *Id.* at 586.

22 Brief for the United States as Amicus Curiae Supporting Respondent at 24, *Mensing*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501) (citing 21 C.F.R. § 201.57(e) (2012)).

23 *Id.*

24 *Mensing*, 131 S. Ct. at 2578.

25 *See id.* (“Indeed, [plaintiffs] deny that their state tort claims are based on the Manufacturers’ alleged failure to ask the FDA for assistance in changing the labels.”). For support, the Court cited the respondent’s brief and (with a “*Cf.*” or compare) *Buckman*, which the Court described as “holding that federal drug and medical device laws pre-empted a state tort-law claim based on failure to properly communicate with the FDA.” *Id.*

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

In an amicus brief in *Bartlett*, the Government proposed a hypothetical state-law “misbranding” tort that would parallel the federal misbranding provision. Under the FDCA, a drug is misbranded “[i]f it is dangerous to health in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.”<sup>27</sup> According to the Government, “appropriate state law actions that parallel the FDCA’s ‘misbranding’ prohibition would not be preempted. Under that prohibition, a manufacturer has a federal duty not to market the drug if . . . it is ‘dangerous to health’ when used as provided in the labeling.”<sup>28</sup>

What might such a state misbranding tort look like? In *Ezagui v. Dow Chemical Corp.*,<sup>29</sup> the Second Circuit found that the warning on the package insert for a vaccine violated the FDCA’s misbranding provision as well as a New York State misbranding law, where the state law was identical to section 352 of the FDCA.<sup>30</sup> Because the plaintiff (an infant) was “clearly within the class of those people who are the intended beneficiaries of these statutes,” he was also entitled to an instruction of negligence per se under New York law.<sup>31</sup> For additional insight, we turn to analyzing a raft of statutory food mislabeling cases.

## B. Statutory Actions

Certain food misbranding claims exemplify state statutory duties that are “parallel” to federal requirements. In this context, California has become the epicenter of lawsuits against food companies for misbranding and misrepresentation. The FDCA prohibits misbranding of food; food “shall be deemed to be misbranded” under the FDCA if “its labeling is false or misleading in any particular.”<sup>32</sup> The Nutrition Labeling and Education Act of 1990 annexed to the FDCA contains an express preemption provision that prohibits states from imposing requirements for food that are not “identical” to

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27 21 U.S.C. § 352(j) (2012).

28 Brief for United States as Amicus Curiae Supporting Petitioner at 23, *Bartlett*, 133 S. Ct. 2466 (No. 12-142).

29 *Ezagui v. Dow Chem. Corp.*, 538 F.2d 727 (2d Cir. 1979).

30 21 U.S.C. § 352 (“A drug or device shall be deemed to be misbranded . . . if the labeling is false or misleading in any particular . . . . The term ‘labeling’ means all labels and other written, printed, or graphic matter . . . accompanying such article.”); N.Y. EDUC. LAW § 6815(2) (McKinney’s 2013) (“A drug or device shall be deemed to be misbranded . . . if its labeling is false or misleading in any particular.”).

31 *Ezagui*, 538 F.2d at 733.

32 21 U.S.C. § 343(a).

the federal requirements.<sup>33</sup> The California Sherman Food, Drug, and Cosmetic Law expressly incorporates “all food labeling regulations and any amendments to those regulations adopted pursuant to the FDCA.”<sup>34</sup> Given that the state statute incorporates the federal regulations, actions brought to enforce these state-law statutory duties are thus “parallel” to the federal requirements.<sup>35</sup>

In a prototypical case of this variety, *In re Farm Raised Salmon Cases*,<sup>36</sup> plaintiffs sued various grocery stores for failing to disclose to customers the use of color additives in salmon. The California Supreme Court held that there was no express preemption because the FDCA allows claims that are “identical” to federal regulations.<sup>37</sup> The plaintiffs’ state-law action was deemed to be based on “parallel” state laws that mirror the relevant sections of federal law.<sup>38</sup>

These cases suggest that, where a plaintiff can show “parallel requirements,” preemption challenges are sure to fail. But this is not entirely true. If the “parallel requirements” demand is the Scylla of contemporary preemption analysis, then the shadow of *Buckman* implied preemption (described in the next Part) is the looming Charybdis.

## II. ENFORCEMENT PREEMPTION

Every products liability case (whether it involves medical devices, pharmaceuticals, or food) that survives a preemption challenge involves some degree of second-guessing an agency determination that a product is safe and effective for consumer use. Even if a state-law “parallel requirements” claim were not an end run around the absence of a private statutory right of action to enforce the FDCA, it might nonetheless tread upon the federal agencies’ discretionary enforcement. Indeed, one could argue that the reason Congress granted exclusive enforcement authority to the FDA was not only to establish a uniform federal regulatory framework, but also to strike a balance that both promotes safety and ensures the development of innovative devices. Enforcement by private parties via state tort lawsuits, by contrast, could

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33 *Id.* § 343-1(a).

34 CAL. ANN. HEALTH & SAFETY CODE § 110740 (2012).

35 Indeed, one might think that state statutory law is even more deserving of preservation than state common-law tort standards, as elaborated by juries under negligence or strict liability theories.

36 *In re Farm Raised Salmon Cases*, 175 P.3d 1170 (Cal. 2008).

37 *Id.* at 1184.

38 *Id.* at 1178.

jeopardize public health by permitting lay juries to second-guess the FDA's expert regulatory judgment.

Just how far can a tort lawsuit — whether common law or statutory — encroach upon an agency's territory? The U.S. Supreme Court provided a preliminary answer in its unanimous 2001 decision in *Buckman Co. v. Plaintiffs' Legal Committee*.<sup>39</sup> In *Buckman*, a regulatory consultant to a medical device manufacturer allegedly made false statements to the FDA in the process of obtaining approval for orthopedic bone screws.<sup>40</sup> The plaintiffs characterized their claims as “claims arising from violations of FDCA requirements.”<sup>41</sup> But there is no federal private right of action under the FDCA.<sup>42</sup> The Court thus held that state-law “fraud on the FDA” claims, based on violations of the Medical Device Amendments (MDA) to the FDCA, were impliedly preempted.<sup>43</sup>

The Court insisted that the lack of a private statutory right of action provided “clear evidence that Congress intended the MDA to be enforced exclusively by the Federal Government.”<sup>44</sup> To survive federal preemption, the Court suggested that the state common-law tort action must be based on “traditional state tort law which had predated the federal enactments in question,”<sup>45</sup> not “solely [on] the violation of FDCA requirements.”<sup>46</sup> In other words, the state tort interest must reach beyond the exclusive *federal* interest in policing fraud against federal agencies.

State-law claims that pass the “parallel requirements” test may be particularly susceptible to *Buckman* implied preemption — indeed, a state-law claim's reliance on the violation of federal requirements to establish the parallel nature of the state and federal standards may fall right into *Buckman*'s prohibition

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

40 *Id.* at 343, 346.

41 *Id.* at 352.

42 21 U.S.C. § 337(a) (2012) (“[A]ll such proceedings for enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.”).

43 Although the district court decision in the case held that the MDA's express preemption provision provided an additional source of preemption, *Buckman*, 531 U.S. at 347, the Supreme Court “express[ed] no view on whether these claims are subject to express preemption,” *id.* at 348 n.2.

44 *Id.* at 352 (citing 21 U.S.C. § 337(a) (2012)); *id.* at 349 n.4 (“The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions.”).

45 *Id.* at 353.

46 *Id.* at 352. In a rather looser formulation than based “solely” on violation of FDCA requirements, the Court suggested that claims in which the violation of the FDCA requirements is a “critical element” of the plaintiff's case would likewise be prohibited. *Id.* at 353.

against state-law claims arising solely on federal statutory violations. Indeed, a very broad reading of *Buckman* leads to the conclusion that most, if not all, of the new state-law “parallel requirement” torts (be they common law or statutory) conflict with the FDCA’s exclusive and discretionary enforcement scheme, and thus are preempted.<sup>47</sup>

But this overly broad interpretation of *Buckman* is flawed. As a doctrinal matter, the more accurate reading recognizes the specific context in which the case arose — alleged fraud on the FDA — and that policing fraud against federal agencies — not “a field which the States have traditionally occupied” — is a distinctly federal interest.<sup>48</sup> In other words, the holding in *Buckman* is best understood as driven by the absence of an independent state-law interest up against a weighty federal interest, because the state-law claim existed solely by virtue of defendant’s alleged violations of federal requirements. On this view of *Buckman*, plaintiffs can “thread the needle” of the two-sided preemption challenge to show that defendant has violated the FDCA, but that plaintiffs’ claims are not entirely premised on that violation. Defendant’s wrongdoing would entitle plaintiff to recover under traditional state-law principles. This requires courts to examine closely, and balance against one another, the respective state and federal interests at stake in a particular case — as illustrated in the following sections.

### A. State Interest

In most U.S. jurisdictions, the lack of a statutory private right of action does not preclude state-law negligence per se actions.<sup>49</sup> Indeed, this is the quintessential “parallel requirements” scenario, whereby state common law enforces an identical federal requirement. To bring a state-law tort suit, a plaintiff must establish the existence of a state-law duty. While states may not be concerned about protecting federal agencies, states do have a strong

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47 *See id.* at 348 (“The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives.”).

48 The Court treated the FDA as the master of the relatively limited domain of agency fraud claims, given that policing fraud against federal agencies is not “a field which the States have traditionally occupied.” *Id.* at 347-48. As the Court explained: “To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character; the relationship originates from, is governed by, and terminates according to federal law.” *Id.*

49 *See supra* note 9 and accompanying text.

interest in protecting their citizens from fraud and personal injuries.<sup>50</sup> But surviving preemption takes more than framing the harm as against consumers as opposed to the agency; in other words, the claim cannot be a fraud-on-the-agency claim in disguise.

Courts must analyze whether a claim is based on “traditional” state law, or whether there is an “independent” state tort law duty. Consider a state common-law negligence claim for failure to update the FDA. So framed, that claim is ostensibly based on a federal duty to update rather than an independent state-law duty. State law, as a general matter, does not require the manufacturer of a generic drug, for example, to update its labeling to match its branded equivalent. For a state-law claim to survive, the claim must be premised on conduct that both “(1) violates FDCA and (2) would give rise to recovery under state law even in the absence of the FDCA.”<sup>51</sup>

But the Ninth Circuit in *Stengel* and the Sixth Circuit in *Fulgenzi* (both discussed above) resisted this characterization. In *Stengel*, the medical device manufacturer argued that the plaintiffs’ failure-to-warn claim sought “to enforce an exclusively federal requirement and [was] not based on traditional state tort law because Arizona law has never required adverse events to be reported to the FDA.”<sup>52</sup> The Ninth Circuit, rejecting this argument, took a much broader view of the relevant state-law interest: “There is no question that state law has an important and legitimate role to play in regulating the adequacy of post-sale warnings for products already on the market.”<sup>53</sup>

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50 See, e.g., *In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 899 (D. Minn. 2006).

51 *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009); see also J. David Prince, *The Puzzle of Parallel Claims, Preemption, and Pleading the Particulars*, 39 WM. MITCHELL L. REV. 1034, 1050, 1084 (2013) (discussing recent preemption decisions, negligence per se cases, and noting that the contours of the “narrow gap” for parallel state actions are unclear).

52 *Stengel*, 704 F.3d at 1235.

53 *Id.* The Seventh Circuit made a similar link between the federal duties imposed by the MDA and state-law tort duties:

The MDA defines an “adulterated” device as a device “not in conformity with applicable requirements or conditions.” . . . While there may not be a “traditional state tort law” claim for an “adulterated” product in so many words, the federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dangers with their products by complying with federal law. The evidence showing a violation of federal law shows that the device is adulterated and goes a long way toward showing that the manufacturer breached a duty under state law toward the patient.

*Bausch v. Stryker*, 630 F. 3d 546, 557 (7th Cir. 2010).

In *Fulgenzi*, the Sixth Circuit described the federal duty of sameness invoked by the plaintiff as “not essential to her case — but only to avoid preemption under *Mensing*.”<sup>54</sup> With respect to the state-law interest, defendants charged that plaintiff’s claim amounted to a “failure-to-*inadequately-warn*” claim that no state law would recognize (because the revision of the label to conform with the brand-name label would still not satisfy the broader state-law duty to provide adequate warnings — a claim which itself would be preempted under *Mensing*).<sup>55</sup> In response, the court remarked: “[T]here is nothing in the Ohio product-liability law inconsistent with a claim that a defendant failed to warn, even inadequately.”<sup>56</sup>

Though the doctrinal test is clear — whether there is a genuine state-law interest at stake (whether termed a “traditional” or “independent” state tort law duty) — it is nearly impossible to discern consistency, let alone coherence, in courts’ application of this test.

## B. Federal Interest

There is a modern judicial reluctance to infer private rights of action from the breach of statutory duties created under complex administrative schemes such as the FDCA. Section 337(a) — enacted as part of the FDCA in 1938 and extended by the MDA in 1976 to medical devices — goes even further and establishes expressly that there is no private right of action to enforce the FDCA.<sup>57</sup>

The Ninth Circuit emphasized this sphere of federal control in *Perez v. Nidek Co., Ltd.*,<sup>58</sup> where the court employed three distinct readings of *Buckman*. The plaintiff sued the manufacturer of an eye laser, alleging that it had misled consumers by not informing them that the FDA had not approved the laser for a particular type of surgery.<sup>59</sup> After finding that the plaintiff’s claim “exist[s]

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54 *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 587 (6th Cir. 2013).

55 *Id.*

56 *Id.* An Iowa state court decided to the contrary that a failure to update claim is “an attempt to skirt the effect of *Mensing*.” *Huck v. Trimark Physicians Grp.*, 2013 WL 1749774, at \*3 (Iowa Ct. App. Apr. 24, 2013). The court also stated (contra *Fulgenzi*) that state law does not provide a cause of action for failing to disseminate allegedly inadequate warnings. Although the Iowa court did not invoke *Buckman*, it nonetheless suggested that the claim was solely based on federal regulations.

57 21 U.S.C. § 337(a) (2012).

58 *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109 (2013).

59 *See id.* at 1117.

solely by virtue of the FDCA . . . requirements”<sup>60</sup> and that “the existence of these federal enactments is a *critical element* in [the plaintiffs’] case,”<sup>61</sup> the court appeared to embrace the broadest possible reading of *Buckman* in holding that the “fraud by omission claim is impliedly preempted because it conflicts with the FDCA’s enforcement scheme.”<sup>62</sup>

But the preemptive power of federal interests is unclear. If *Buckman* bars private enforcement of the FDCA, does it also bar private enforcement of state provisions identical to those in the FDCA? In the *Stengel* medical device case (described above), for example, does the use of general principles of state law to enforce federal reporting requirements conflict with 21 U.S.C. § 337(a), which provides that the MDA must “be enforced exclusively by the Federal Government”?<sup>63</sup> The doctrinal approach illustrated by these cases is unsatisfying and often raises more questions than answers. In particular, courts’ determinations of what amounts to a sufficient independent state interest and/or an overriding competing federal interest are inconsistent and rudderless.

To search for a new paradigm for decision-making, it is worth recalling that, at its core, *Buckman* implied preemption seeks to determine the extent to which a tort lawsuit — whether common law or statutory — encroaches upon an agency’s territory. In *Buckman* itself, the Supreme Court concededly used rather sweeping language to characterize the potential clash between state tort liability and federal enforcement policy: “State-law fraud-on-the-FDA claims *inevitably conflict* with the FDA’s responsibility to police fraud consistently with the Administration’s judgment and objectives.”<sup>64</sup> Moreover, the Court was concerned about state courts’ (and presumably juries’) ability to second-guess the FDA’s expert determination that the federal regulatory requirements were satisfied.<sup>65</sup> The Court’s underlying reasoning points to

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60 *Id.* at 1119 (emphasis added) (quoting *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 353 (2001)).

61 *Id.* (emphasis added) (quoting *Buckman*, 531 U.S. at 352).

62 *Id.* The court reiterated the agency’s ability to enforce its provisions through injunction proceedings, civil and criminal penalties, and seizure — and the court is correct in noting that these types of sanctions, and the ability of the FDA “to punish and deter fraud,” were crucial to the decision in *Buckman*. *Id.*; see also *Buckman*, 531 U.S. at 347-50 (discussing FDA’s enforcement mechanisms and noting that flexibility is a key component of its regulatory framework).

63 *Buckman*, 531 U.S. at 352.

64 *Id.* at 350 (emphasis added).

65 See *id.* at 351 (“[F]raud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court.”). The Court added: “As a practical matter, complying with the FDA’s detailed regulatory



a new paradigm of tort-agency partnerships, whereby federal agencies are called upon to weigh in on the pros and cons (or benefits and costs) of parallel state-law enforcement of federal requirements in a context-specific manner.

### III. TORT-AGENCY PARTNERSHIPS?

At the core of these controversies regarding the viability of state tort law claims in the shadow of preemption is the extent to which state tort law actions tread upon, as opposed to supplement or facilitate, federal enforcement of health and safety standards. A key theme that emerges is that courts should prevent private parties from undermining, through private litigation, the FDA's reasoned judgments. Courts will be best equipped to make such determinations by soliciting input on the matter from the FDA itself.

I have previously emphasized the role federal agencies should play in courts' framework for deciding whether state-law standards conflict with federal ones (i.e., the first wave of products liability preemption cases): "With respect to answering the key regulatory policy issue at the heart of the preemption query — namely, whether there in fact should be a uniform federal regulatory policy — federal agencies emerge as the institutional actor best equipped to provide the answer."<sup>66</sup> More specifically,

[a]gencies can serve as a reference in determining the optimal regulatory strategy; specifically, agencies conduct context-specific cost-benefit (or risk-risk) analyses in deciding whether or not to pass regulations. This information base, moreover, can provide an empirical basis for the Court's assessment as to whether a uniform federal regulatory policy should exist in a particular area.<sup>67</sup>

The "normative mooring" of my view is "an amalgam of the conventional 'expertise' and 'uniformity' rationales for reliance on, or deference to, agencies."<sup>68</sup> That said, courts, in addressing products liability preemption disputes, must

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regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants — burdens not contemplated by Congress in enacting the FDCA and the MDA." *Id.*

66 Sharkey, *Products Liability Preemption*, *supra* note 4, at 477; accord Catherine M. Sharkey, *Drug Advertising Claims: Preemption's New Frontier*, 41 *LOY. L.A. L. REV.* 1625 (2008) [hereinafter Sharkey, *Drug Advertising Claims*].

67 Sharkey, *Products Liability Preemption*, *supra* note 4, at 497.

68 *Id.* at 485.

not only solicit — but then also must scrutinize — input from the underlying federal regulator on these fundamental questions.<sup>69</sup>

Over the past two decades of products liability preemption decisions, the role of the underlying regulator has increasingly come to the fore in the U.S. Supreme Court’s analysis. The Court’s decisions tracked the federal regulator’s position fairly consistently — at first, *sub silentio*, without express mention of the agency, but then as part of a more established framework according a “power to persuade” deference (pursuant to the administrative law deference standard of *Skidmore*) to the agency’s position.<sup>70</sup> As the Supreme Court has recognized, the FDA in particular “is uniquely qualified to determine whether a particular form of state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’”<sup>71</sup> Agencies, to quote Justice Stephen Breyer, have a “special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether . . . state requirements may interfere with federal objectives.”<sup>72</sup>

In this Article, I advocate the extension of my agency reference model to the “enforcement preemption” context. Courts should place more emphasis on FDA input when deciding if tort requirements are “parallel” to federal dictates, and (perhaps even more so) whether, even if the state claims are parallel, they nonetheless infringe on the federal agency’s discretionary enforcement prerogatives. The upshot of my position is that courts would seek guidance

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69 *See id.*; *see also* Sharkey, *Drug Advertising Claims*, *supra* note 66, at 1626:

[C]ourts should look to agencies to supply the data and analysis to determine when a uniform national regulatory policy with respect to a certain product makes the most sense or, instead, whether such a regulation is better left to the states — in which case a plaintiff’s common law claim should be permitted to proceed.

Significantly, my “institutional approach” to preemption moves away from the “presumption against preemption” approach. In rather sharp contrast, my approach instead “places federal agencies front and center.” *See* Sharkey, *Products Liability Preemption*, *supra* note 4, at 453.

70 *See, e.g.*, Sharkey, *Products Liability Preemption*, *supra* note 4, at 491-502 (citing *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944)). Most recently, however, the Court has tilted toward a more formalist, statutory interpretation model that foregoes deference to the agency. *See, e.g.*, *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2475-76 (2013) (locating generics’ “duty of sameness” under the statute (FDCA) and FDA regulations as the basis of its holding that it was impossible for the manufacturer to avoid liability under New Hampshire law).

71 *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

72 *Id.* at 506 (Breyer, J., concurring).

from federal agencies on essentially whether a private right of action exists for the state enforcement of federal regulations.<sup>73</sup>

### A. State Enforcement of Prior Agency Determinations

Viewed through this agency-focused lens, one category of state-law cases should emerge as non-preempted “parallel” state claims: where the federal agency has made a prior determination (whether of fraud on the agency, or misbranding), a state-law claim should then be allowed to proceed on the basis of that determination — putting to one side (for now) the separate issue of the agency’s discretionary enforcement prerogative.<sup>74</sup>

This was the gist of Justice John Paul Stevens’s concurrence (joined by Justice Clarence Thomas) in *Buckman*: where the FDA had previously found that a manufacturer committed fraud against the agency, a state-law claim premised on that antecedent finding should proceed.<sup>75</sup> In that circumstance,

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73 This is a step in the direction of rectifying what I have previously identified as a “potentially troubling asymmetry [whereby] courts appear to grant agencies fairly expansive discretion to interpret or declare the preemptive scope of the regulations they promulgate, but when it comes to inferring private rights of action under those same regulations, the agencies’ hands are tied by the judicial tether.” Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 228-29 (2007). My proposal here resonates with Matthew Stephenson’s call to expand the role of agencies in reading private rights of action into the federal statutes that they administer. See Matthew C. Stephenson, *Public Regulation of Private Enforcement: The Case for Expanding the Role of Administrative Agencies*, 91 VA. L. REV. 93, 148 (2005). But it differs in two key respects. First, Stephenson is focused on federal agencies’ role in establishing federal private rights of action, whereas my focus is on soliciting input from federal agencies on the appropriate balance between federal and state-law enforcement of federal standards. Second, Stephenson would have courts accord *Chevron* (or mandatory) deference to agencies’ determination that a federal private right of action exists, whereas in my framework, courts should only accord *Skidmore* (or power to persuade) deference to the federal agency’s view — and should scrutinize the input accordingly. See *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984) (describing two-step test for mandatory deference); *Skidmore*, 323 U.S. at 140 (noting criteria for power to persuade deference).

74 For a more detailed account of this position, see Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 NW. U. L. REV. 841 (2008).

75 See *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 354 (2001) (Stevens, J., concurring) (“If the FDA determines both that fraud has occurred and that such fraud requires removal of a product from the market, state damages remedies

the state-law tort action complements the federal agency determination; at least, it does not rest on any counterfactual regarding how the agency would have proceeded had the manufacturer's information disclosure been more forthright.

A direct corollary to the *Buckman* concurrence applies in the context of state-law design defect and failure-to-warn claims in the medical device and drug arenas. Consider *Lefaiivre v. KV Pharmaceutical Co.*,<sup>76</sup> a case where a complaint filed by the FDA in 2009 against drug manufacturer KV led to a jointly filed consent decree between the FDA and KV.<sup>77</sup> As part of the consent decree, KV stipulated that its drugs were "adulterated."<sup>78</sup> A plaintiff subsequently filed suit for breach of implied warranty of merchantability and for violating the Missouri Merchantability Practices Act based upon the manufacturer's failure to comply with federal regulations.<sup>79</sup> The federal district court dismissed the state-law claims on *Buckman* grounds, stating that the claims were based entirely on federal regulations.<sup>80</sup> The Eighth Circuit, however, reversed on the ground that the state-law claims were not "dependent upon speculation as to the FDA's behavior," but instead were "grounded in the agency's explicit actions."<sup>81</sup>

Taking this idea of a partnership between FDA action and state-law tort claims a step further, courts should rely on input from the FDA in areas where the FDA has not taken any prior action.

## B. Enforcement Preemption: A Partnership Approach

State enforcement might complement federal enforcement or else be at odds with federal prerogatives and aims — and this might vary from context to context. Consider, for example, regulation of immigration and alien registration. At stake in *Arizona v. United States*, a provision of Arizona law created a misdemeanor offense for the "willful failure to complete or carry out an alien registration document" in violation of federal law.<sup>82</sup> Essentially a parallel requirement created by Arizona, the provision "add[ed] a state-law penalty

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would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme.").

76 *Lefaiivre v. KV Pharm. Co.*, 636 F.3d 935 (8th Cir. 2011).

77 *Id.* at 937.

78 *Id.*

79 *Id.*

80 *Id.* at 938; *Lefaiivre v. KV Pharm. Co.*, 2010 WL 59125 (E.D. Mo. Jan. 5, 2010).

81 *Lefaiivre*, 636 F.3d at 943-44 (quoting *Buckman*, 531 U.S. at 354 (Stevens, J., concurring)).

82 *Arizona v. United States*, 132 S. Ct. 2492, 2497-98 (2012).

for conduct proscribed by federal law.<sup>83</sup> The Government argued in favor of preemption in *Arizona*, claiming that state-law enforcement of federal immigration law would be at odds with the Government's discretionary enforcement policy. In its brief to the Court, the Government pressed a field preemption view of *Buckman*:

[I]n exclusively federal contexts like this one, a State has no inherent power to supplement the punishment for an offense solely against the United States. . . . The holding of *Buckman* . . . indisputably refutes petitioners' bold assertion that "parallel" tort claims are "easy cases" for non-preemption merely because "both state and federal law enforce the same standard." As *Buckman* illustrates, a state law may interfere with a balanced federal approach even without setting a different substantive standard.<sup>84</sup>

The Supreme Court held that Congress had "occupied the field of alien registration" and therefore "[p]ermitting the State to impose its own penalties for the federal offenses here would conflict with the careful framework Congress adopted."<sup>85</sup> Indeed, the Court followed this statement with a citation (albeit "Cf." or compare) to *Buckman*.<sup>86</sup>

In other areas, the Government seeks out enforcement partners. In the arena of promotion and marketing of approved pharmaceutical drugs, for example,

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83 *Id.* at 2501.

84 Brief for Respondent at 27-28, *Arizona*, 132 S. Ct. 2492 (No. 11-182) (citations omitted).

85 *Arizona*, 132 S. Ct. at 2502.

86 *Id.* at 2502-03. Adam Cox describes Arizona's immigration law as a "classic example of enforcement redundancy" that, under the norm of allowing redundant enforcement, should survive preemption. Adam B. Cox, *Enforcement Redundancy and the Future of Immigration Law*, 2012 SUP. CT. REV. 31, 48 (2012). Cox concludes that "applying the Court's approach [of treating the law as a price rather than an obligation] broadly would collapse conflict preemption into field preemption and destroy broad swaths of state regulatory authority." *Id.* at 55. I agree with Cox's conclusion here — namely that what I have termed "enforcement preemption" transforms conflict preemption into field preemption — but, to my mind, the Court's approach is guided by its conception of the "plenary" nature of the regulation of immigration and alien registration. In other words, exercising what Kerry Abrams has called "plenary power preemption," the Court struck down all but one of the key provisions of Arizona's immigration law, commonly known as S.B. 1070. Pursuant to the plenary power doctrine — "one of the oldest features of immigration law" — the Court accords extraordinary deference to federal and executive action in immigration matters. Kerry Abrams, *Plenary Power Preemption*, 99 VA. L. REV. 601, 602-03 (2013).

the FDA has not only “adopted aggressive enforcement policies” against manufacturers who violate the misbranding strictures of the FDCA, but the agency has also “enlisted the assistance of the FTC, several state attorneys general, and the Office of Inspector General in pursuit of its mission.”<sup>87</sup>

Especially given the force of the arguments made in *Buckman* regarding the need to preserve the agency’s discretionary enforcement authority and, specifically, the need to avoid overburdening the agency,<sup>88</sup> it is confounding that courts do not, as a matter of course, check such arguments against solicited input from the relevant agency. An agency should be in the best position to decide, from an administrative perspective, whether a state private right of action for violation of its regulation would actually create such burdens and costs. Courts should not, however, accept input from the relevant agency uncritically. Instead, courts must scrutinize such input from the agency to ensure that it is backed by credible factual and policy evidence.<sup>89</sup>

The U.S. Supreme Court has (albeit gradually) come to rely on the position of the underlying federal regulator in making preemption determinations. In *Wyeth v. Levine* (which found no preemption of state-law claims against brand-name drug manufacturers), for example, the Court was influenced by the fact that “the FDA traditionally regarded state law as a complementary

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87 Thomas A. Hayes, *Drug Labeling and Promotion: Evolution and Application of Regulatory Policy*, 51 FOOD & DRUG L.J. 57, 73 (1996).

88 Recall that in *Buckman* the Court justified its decision to preempt plaintiff’s fraud-on-the-FDA claim on the grounds that it would (1) interfere with the agency’s delicate and flexible approach to deterring fraud; (2) increase the burdens on manufacturers who would comply with federal regulations and still face potential tort liability in fifty different states, thereby discouraging off-label use; and (3) increase the burdens on the agency because manufacturers, out of a fear that their submissions would later be deemed insufficient in state court, would submit a “deluge of information the [agency] neither wants nor needs.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 351 (2001).

89 In prior work, I analyzed an apt example in the consumer fraud / drug advertising context. See Sharkey, *Drug Advertising Claims*, *supra* note 66, at 1642-45 (discussing intervention by the United States, on behalf of the FDA, at the California federal district court’s request in a case involving consumer fraud claims stemming from the alleged misleading advertisements of a prescription drug). I argued that the court rightly rejected the Government’s argument that the FDA’s administration of a “comprehensive national regulatory scheme” governing prescription drug advertising in essence preempted the field, displacing state-law enforcement of consumer fraud claims. *Id.* at 1643. In that case, the Government’s claim was patently at odds with the limited nature of the FDA’s regulatory review of prescription drug advertisements. *Id.* at 1645, 1637-40 (describing the FDA’s lax regulation of prescription drug advertising).

form of drug regulation. . . . [T]he FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.”<sup>90</sup>

Direct agency input and the primary jurisdiction doctrine shed light on how agency positions might be effectively incorporated into courts’ decisions on preemption.

### 1. Federal Agency Input

#### i. Complementary State Enforcement

In its amicus brief in *Mensing*, for example, the Government (representing the FDA) sought to distinguish *Buckman* from the case at hand:

[T]he fraud-on-the-FDA issues in . . . *Buckman* . . . impermissibly intruded on federal law because they constituted a collateral attack on a decision actually made by FDA in the past — thus they entailed second-guessing FDA decisionmaking on an issue actually presented to it and a difficult inquiry into [the] counterfactual situation would have existed absent the fraud. . . . By contrast, the appropriate inquiry here addresses whether petitioners’ drugs violated substantive misbranding and regulatory standards based on *new information not presented to FDA*.<sup>91</sup>

Again, in its amicus brief in *Bartlett*, in setting forth the hypothetical state-law “misbranding tort” that would escape preemption, the Government suggested that “new and scientifically significant information” should be required. Specifically, in the context of drug cases, the Government suggested that if a “pure” design-defect claim (i.e., one that does not take into account the warning/label on the drug, such as that proposed by the *Restatement Third: Products Liability*) is based on “new and scientifically significant evidence”

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90 *Wyeth v. Levine*, 555 U.S. 555, 578-79 (2009). Applying the *Skidmore* power to persuade standard, *see supra* notes 70, 73 and accompanying text, the Court rejected the FDA’s assertion of preemption in the case at hand, in part because “it reverses the FDA’s own longstanding position without providing a reasoned explanation, including any discussion of how state law has interfered with the FDA’s regulation of drug labeling during decades of coexistence.” *Id.* at 577.

91 Brief for the United States as Amicus Curiae Supporting Respondent at 31-32, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501) (emphasis added).

that renders the drug “misbranded” under federal law, the design defect claim should not be preempted.<sup>92</sup>

In principle, such a situation, where new risk evidence has come to light that was not yet considered by the FDA, either in its initial approval or any subsequent review, is precisely where state tort law claims could play a value-added role, in terms of bringing such new risk evidence to light.

## ii. Conflicting State Enforcement

An approach centered on input from the federal agency will admittedly have some problems. One issue is the extent to which state action prying into agency decision-making processes would, by its very nature, impose unnecessary costs and overburden the federal agency. Specifically, to what extent would the FDA become enmeshed in civil litigation, where, for example, litigants would attempt to take depositions of examiners to find out what went on at the FDA, what kinds of evidence examiners considered, etc. The specter of increasing the burden on the agency was, after all, a core concern of the Court in *Buckman*.<sup>93</sup>

But here is where it seems almost nonsensical for courts to assume and take steps to avoid these hypothetical burdens on the agency, absent hearing directly from the agency itself. Agencies might differ with respect to inherent

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92 Brief for the United States as Amicus Curiae Supporting Petitioner at 20-21, *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013) (No. 12-142). The respondent in *Bartlett* seized on the Government’s misbranding theory by noting that the jury had access to an unpublished Pharmacia Report that exposed the risks of Sulindac, while the FDA did not have this information. Brief for Respondent at 1, 52-53, 57, *Bartlett*, 133 S. Ct. 2466.

Significantly, the Government did note that private lawsuits *may* interfere with the agency’s regulatory and enforcement scheme:

In the face of this elaborate regulatory regime [under the FDCA] instituted to safeguard the national market and protect consumers throughout the United States, and the extensive commitment of public and private resources to those ends, it would be inconsistent with the FDCA to conclude that a manufacturer must abandon a market it has been approved by FDA to enter to avoid violating a duty recognized by a jury under state tort law that deems its product unsafe.

Brief for the United States as Amicus Curiae Supporting Petitioner at 27-28, *Bartlett*, 133 S. Ct. 2466 (No. 12-142).

93 *Buckman*, 531 U.S. at 351 (reasoning that fraud-on-the-FDA claims would give applicants “an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA’s evaluation of an application”).



tradeoffs between subjecting themselves to some burden in exchange for capitalizing on the complementary role that state tort law might play as a catalyst for uncovering new risk information. In *Mensing*, for example, the Government stated that the FDA expected only a “modest burden from an inquiry in tort litigation into misbranding.”<sup>94</sup> To my mind, that should be sufficient to address *Buckman*’s concern about infringing on the agency’s turf.

Situations of agency inaction pose more difficult problems. Should state tort law always be able to proceed in the face of no prior determinations by the relevant federal agency? Wouldn’t this potentially intrude upon the agency’s discretionary enforcement power? Here, too, courts should attempt to ground their decisions by inquiring into the reasons behind the agency’s inaction.<sup>95</sup>

One California federal district court’s approach is illustrative. In *Ivie v. Kraft Foods Global, Inc.*,<sup>96</sup> the plaintiff brought claims for food misbranding under the California Sherman Food, Drug, and Cosmetic Law for allegedly misleading representations that the defendant’s products were “natural” and contained “no artificial” ingredients. The court looked first to whether or not the manufacturer complied with the relevant federal regulations. With respect to the claim that the “natural” label was misleading, the court relied on a statement from the FDA (made in one of its official regulations): “Because of resource limitations and other agency priorities, FDA is not undertaking rulemaking to establish a definition for ‘natural’ at this time.”<sup>97</sup> In the face of FDA’s inaction — inaction that the FDA specifically attributed to resource constraints — the court concluded that allowing the claim to go forward “would not risk undermining the agency’s expertise in the area.”<sup>98</sup>

## 2. Primary Jurisdiction

Under the doctrine of primary jurisdiction, a court may “refer a matter extending beyond the ‘conventional experiences of judges’ or ‘falling within the realm of

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94 Brief for the United States as Amicus Curiae Supporting Respondent at 34, *Mensing*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501).

95 See also Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 103 Nw. U. L. REV. 437, 441, 447-48 (2009) (arguing that “courts need a fine-grained account of the precise regulatory review conducted by the agency and evidence as to its compatibility with state tort claims” and must then “undertake judicial review probing the adequacy of reasons given by the agency for taking a particular action, as well as for changing tack and taking a different course of action”).

96 *Ivie v. Kraft Foods Global, Inc.*, 2013 WL 685372 (N.D. Cal. Feb. 25, 2013).

97 *Id.* at \*13 (quoting 58 Fed. Reg. 2302, 2407 (1993)).

98 *Id.*

administrative discretion' to an administrative agency with more specialized experience, expertise, and insight."<sup>99</sup> Courts tend to apply primary jurisdiction to cases raising "technical and intricate questions of fact and policy that Congress has assigned to a specific agency."<sup>100</sup> The effect is that "the judicial process is suspended pending referral of such issues to the administrative body for its views."<sup>101</sup>

Primary jurisdiction is a bit of an enigma in U.S. jurisprudence. In characterizing the doctrine, the U.S. Supreme Court gave it a distinctly functional gloss: "No fixed formula exists for applying the doctrine of primary jurisdiction. In every case the question is whether the reasons for the existence of the doctrine are present and whether the purposes it serves will be aided by its application in the particular litigation."<sup>102</sup> The reasons are twofold: a need for the expertise and specialized knowledge of an administrative agency, and a need for consistency and uniformity in a nationally regulated industry.

While courts have thus far rejected invocations of primary jurisdiction in the first wave of products liability preemption cases,<sup>103</sup> the doctrine has gained some traction in the food misbranding cases. First, there is the scenario in which the FDA has yet to weigh in on the particular issue involved. In *Cox v. Gruma Corp.*,<sup>104</sup> a California federal district court considered a putative class action claim alleging that certain foods containing genetically modified organisms, which were labeled as "All Natural," were false and misleading under various California state consumer protection laws.<sup>105</sup> The court noted that the parties were in agreement that the FDA had not addressed, "even informally," the question whether bioengineered and genetically modified foods may be labeled as "natural" or "all natural," or should be considered as

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99 Nat'l Commc'ns Ass'n Inc. v. Am. Tel. & Tel. Co., 46 F.3d 220, 222-23 (2d Cir. 1995) (quoting *Far E. Conference v. United States*, 342 U.S. 570, 574 (1952)).

100 *Id.*

101 *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 64 (1956).

102 *Id.*

103 See Catherine T. Struve, *Greater and Lesser Powers of Tort Reform: The Primary Jurisdiction Doctrine and State-Law Claims Concerning FDA-Approved Products*, 93 CORNELL L. REV. 1039, 1044 (2008) ("[C]ourts are less likely to apply the doctrine to tort suits for personal injury damages."). *But see* *Bernhardt v. Pfizer*, 2000 WL 1738645 (S.D.N.Y. Nov. 22, 2000) (invoking primary jurisdiction in a failure-to-warn case, referring the matter to the FDA to analyze new information that came to light from a study by the National Institute of Health concerning health risks).

104 *Cox v. Gruma Corp.*, 2013 WL 3828800 (N.D. Cal. July 11, 2013).

105 *Id.* at \*1.

“artificial” or “synthetic.”<sup>106</sup> Given the dearth of administrative guidance on the issue, the court concluded that “deference to the FDA’s regulatory authority is the appropriate course” and thereby referred the matter to the agency.<sup>107</sup> Likewise, in a class action filed against nine soft drink manufacturers and distributors, a New York state court referred to the FDA the issues presented concerning the appropriateness of the labeling of beverages containing the artificial sweetener Aspartame on the ground that it “will ensure that there will be national uniformity in the labeling of Aspartame and will utilize the special expertise of the FDA in evaluating the relevant factors for approving food additives.”<sup>108</sup>

Second, there is the scenario in which primary jurisdiction could be a useful tool in situations where there is new information that might convince the agency to revise a previous regulation or guidance document.<sup>109</sup> In other words, the doctrine’s use is premised on the likelihood that the agency may adopt a position different from that in the existing administrative record to date.

Direct input from federal agencies and primary jurisdiction thus offer two alternative avenues for pursuing new forms of tort-agency partnerships in the health and safety realm.<sup>110</sup>

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106 *Id.* at \*2.

107 *Id.* The court ordered the parties to “cooperate in expediting the presentation and explanation of this question to the FDA and [to] notify this Court promptly of any determination by the FDA.” *Id.* In another case, a federal district court in Colorado relied on *Cox* to invoke primary jurisdiction. *See Van Atta v. Gen. Mills, Inc.*, 1:12-cv-02815-MSK-MJW, at \*7 (D. Colo. July 18, 2013) (recommending that “pursuant to the primary jurisdiction doctrine, this case be stayed pending action by the FDA with respect to the referral made . . . in [*Cox*]”).

108 *Heller v. Coca-Cola Co.*, 646 N.Y.S.2d 524 (App. Div. 1996).

109 Consistent with this, courts have rejected calls for primary jurisdiction when they do not anticipate any meaningful change in agency position. *See, e.g., Iams Co. v. Nutro Prods.*, 2004 WL 5780000 (S.D. Ohio July 19, 2004) (rejecting primary jurisdiction where the FDA, having conducted an extensive eighteen-month investigation, concluded — albeit in a letter to a consumer advocacy group — that the dog food manufacturer’s label was neither false nor misleading); *Feinberg v. Colgate-Palmolive Co.*, 34 Misc. 3d 1243A, at \*32-33 (N.Y. Sup. Ct. 2012) (rejecting primary jurisdiction where it is doubtful that the FDA would rule on the safety of a talcum powder cosmetic that is no longer on the market).

110 I have by no means attempted a comprehensive analysis of primary jurisdiction and/or its comparative advantage or disadvantage *vis-à-vis* the agency reference model that seeks input from the relevant agency. But one significant factor would be the costs of delay inherent in primary jurisdiction. A second factor would be the capacity of agencies to entertain such cases on a regular basis. *Cf. Mark Hermann et al., The Meaning of the Parallel Requirements Exception Under*

## CONCLUSION

Necessity breeds opportunity. State-law design defect and failure to warn claims imposing heightened health and safety standards for medical devices and generic pharmaceutical devices are now preempted. A second generation of state-law claims, seeking to enforce “parallel” federal requirements, has emerged in these areas. And now, the “next wave” of preemption cases — what I have termed “enforcement preemption” cases — will test the extent to which state law can impose substantive duties that are “parallel” to federal requirements without encroaching upon a federal agency’s discretionary enforcement prerogative. In these cases, plaintiffs must “thread the needle” of a two-sided preemption challenge, demonstrating that the defendant has violated the FDCA (i.e., a parallel claim that resists express and implied preemption), but at the same time insisting that their claims are not entirely premised upon that violation (i.e., not subject to *Buckman* implied preemption).

At the core of these enforcement preemption cases is the extent to which state tort law actions undermine, as opposed to complement, federal enforcement of health and safety standards. Herein lies the opportunity for new tort-agency partnerships to be forged in the shadow of preemption. In this Article, I advocate the extension of the “agency reference” model to the enforcement preemption context. Courts should place more emphasis on FDA input when deciding whether tort claims are “parallel” to federal requirements as well as whether, even if they are, they nonetheless infringe on the agency’s discretionary enforcement prerogatives. And, in appropriate cases, courts could employ the doctrine of primary jurisdiction as a communication mechanism between courts and agencies.

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Lohr and Riegel, 65 N.Y.U. ANN. SURV. AM. L. 545, 583 n.141 (2010) (“Given the volume of claims relating to medical devices, the range of supposed FDCA violations alleged in those actions, and the fact that primary jurisdiction is to be ‘invoked sparingly,’ it is unlikely that courts would routinely find that primary jurisdiction should be invoked in this context.”).