

# THE PRESUMPTION AGAINST IMPLIED PREEMPTION: HOW STATE LAW FRAUD-ON-THE-FDA CLAIMS COMPLEMENT, RATHER THAN CONFLICT WITH, FEDERAL LAW

HANNAH RODGERS\*

## ABSTRACT

*Imagine an individual who visits his or her doctor after developing a hernia. The doctor informs the individual of a new implant—or mesh—that involves minimally invasive surgery with very little healing time. Many individuals would not hesitate to accept this offer. However, after the surgery, the individual experiences painful side effects and ultimately must undergo subsequent surgeries to remove the defective implant. Following remedial action, the individual files suit against the manufacturer of the implant—or rather the manufacturer of the medical device—alleging multiple state common law claims for monetary compensation and punitive damages for pain and suffering. Whether courts will allow such claims to survive is the focal point of this Note and the current circuit split regarding the preemptive effect of the Medical Device Amendments to the Food, Drug, and Cosmetic Act.*

*While the Medical Device Amendments include an express preemption provision, allowing courts to maneuver within the limits of its possible interpretations, the question of whether claims are impliedly preempted requires a much more technical and in-depth analysis from the courts. Buckman Co. v. Plaintiffs’ Legal Committee laid the framework for the contours of implied conflict preemption, and how and to what extent implied preemption may be invoked. Buckman held that “state-law fraud-on-the-FDA claims” are impliedly preempted by the Medical Device Amendments because, inter alia, such claims “inevitably conflict with the FDA’s responsibility to police fraud consistently with the Administration’s judgment and objectives.” However, this holding is susceptible to attack; state-law fraud-on-the-FDA claims should not be so readily held as preempted. These claims undoubtedly assist the FDA in policing fraud, and such claims should be available for injured plaintiffs when medical device manufacturers fail to fully comply with FDA rules and regulations during premarket approval or postmarket requirements.*

*This Note discusses the unfair and unjust application of implied preemption as applied to state common law claims of fraud-on-the-FDA. Part I will examine the societal need that prompted the creation of the Medical Device Amendments with respect to premarket approval of Class III medical devices. Part II will discuss the current state of the law, addressing the Riegel, Lohr, and Buckman cases, as well as highlight the current split among circuits with regard to implied conflict preemption. Part III proffers that state-law fraud-on-the-FDA claims should ultimately survive preemption and become a readily available avenue for injured plaintiffs to obtain recourse and hold manufacturers responsible for negligent and/or intentional unlawful conduct. Finally, this Note concludes by reiterating the importance of state-tort law in the realm of medical device regulation; for without such common law avenues, medical device manufacturers would be on track to receive complete immunity from tort liability.*

I. INTRODUCTION.....	862
II. THE BIRTH OF THE MEDICAL DEVICE AMENDMENTS .....	863
A. Premarket Approval.....	864
B. Class III Medical Devices and Preemption.....	865
III. MANEUVERING THE LAW .....	869

---

\* J.D. Candidate, Florida State University College of Law. I would like to thank my family for their endless love and support and for always encouraging me to pursue my passions. I would also like to thank David E. Landau and Stephen H. Echsner for their indispensable and invaluable assistance in the development of this Note.

A. Riegel ..... 869

B. Lohr..... 870

C. Buckman..... 872

D. Circuit Split ..... 873

    1. The Fifth, Seventh, and Ninth Circuits..... 874

    2. The Sixth and Eighth Circuits ..... 876

IV. THE RELATIONSHIP BETWEEN THE FDA AND STATE-TORT CLAIMS ..... 879

V. CONCLUSION ..... 887

I. INTRODUCTION

The Tenth Amendment to the United States Constitution reads, “[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively.”<sup>1</sup> This amendment is particularly relevant because up until the enactment of the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDCA), the states held primary authority for regulating and approving new medical devices.<sup>2</sup> The birth of the MDA,<sup>3</sup> however, brought with it a new framework of federal governance that unquestionably scaled back the authority states once had and, arguably, infringed upon states’ rights under the Tenth Amendment.<sup>4</sup> With a new structure in place, states can no longer guarantee, or even fully offer, the same protections they once did with tort liability against manufacturers of medical devices. This is due, in part, to the fact that the MDA has an express preemption provision,<sup>5</sup> which significantly limits the claims a plaintiff may bring against a manufacturer of medical devices solely to “parallel” state law claims.<sup>6</sup> The MDA also restricts state involvement with the doctrine of implied conflict preemption.<sup>7</sup>

Implied preemption has become increasingly more operative within the field of state-tort lawsuits, barring common law claims where

---

1. U.S. CONST. amend. X.

2. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008).

3. The Medical Device Amendments were enacted in 1976. They separated medical devices into three classes—differentiating based on device descriptions, purposes, and the accompanying regulations for each class. 21 U.S.C. § 360c(a) (2012).

4. *See Riegel*, 552 U.S. at 316, 333 (“The Medical Device Amendments of 1976 . . . as construed by the Court, cut deeply into a domain historically occupied by state law.”).

5. 21 U.S.C. § 360k(a) (2012).

6. A parallel claim is a state law that is “premised on a violation of FDA regulations.” *See In re Medtronic Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010).

7. Conflict preemption is appropriately invoked when compliance with both state and federal law is impossible, or when a state law or regulation “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1039 (9th Cir. 2015) (quoting *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985)).

they once would have thrived.<sup>8</sup> The holdings in *Riegel* and *Buckman* significantly impact the scope of preemption by creating a “narrow gap through which a plaintiff’s state-law claim must fit if it is to escape express or implied preemption.”<sup>9</sup> While there is a long-standing notion of the presumption against preemption—which “applies with particular force when Congress has legislated in a field traditionally occupied by the [s]tates”<sup>10</sup>—this presumption, with regard to the MDA and medical device manufacturers, currently seems tenuous at best. Thus, the future of traditional state-tort common law claims is at the mercy of the federal judiciary’s analysis and interpretation of the scope of the MDA; and as shown throughout this Note, there is little consistency among courts as to how and to what extent preemption applies.

## II. THE BIRTH OF THE MEDICAL DEVICE AMENDMENTS

In 1976, Congress amended the FDCA to include the MDA.<sup>11</sup> The enactment of these amendments came about, in part, as a response to rising concerns regarding the safety and efficacy of medical devices, specifically the Dalkon Shield birth control device,<sup>12</sup> and also in part due to the pressing need for uniform regulation, a user-friendly classification system, and overall consistency in approving safe and effective medical devices.<sup>13</sup>

The MDA set forth a three-part classification system to identify the required standards each device must meet within each class.<sup>14</sup> The pertinent discussion for this Note is on Class III devices, which

8. See, e.g., *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1333 (11th Cir. 2017); *Loreto v. Procter & Gamble Co.*, 515 F. App’x 576, 579 (6th Cir. 2013); *Martin v. Medtronic, Inc.*, No. 1:15-cv-00994, 2017 WL 825410, at \*7 (E.D. Cal. Feb. 24, 2017); *Frere v. Medtronic, Inc.*, No. 15-02338, 2016 WL 1533524, at \*7 (C.D. Cal. Apr. 6, 2016).

9. *In re Medtronic, Inc., Sprint Fidelis Leads*, 623 F.3d at 1204.

10. *McClellan*, 776 F.3d at 1039 (quoting *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008)).

11. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

12. Carol H. Krismann, *Dalkon Shield*, *ENCYCLOPEDIA BRITANNICA*, <https://www.britannica.com/science/Dalkon-Shield> [<https://perma.cc/2FQA-3M4Z>] (noting the Dalkon Shield was an intrauterine birth control device that was responsible for a “high number of reported incidents of inflammatory pelvic infections, uterine perforations, and spontaneous septic abortions,” and further noting that four people died as a result of receiving such device); Gregory J. Scandaglia & Therese L. Tully, *Express Preemption and Premarket Approval Under the Medical Device Amendments*, 59 *FOOD & DRUG L.J.* 245, 246 (2004).

13. Gail H. Javitt, *I’ve Got You Under My Skin—And I Can’t Get Redress: An Analysis of Recent Case Law Addressing Preemption of Manufacturer Liability for Class III Medical Devices*, 49 *FOOD & DRUG L.J.* 553, 558-59 (1994).

14. 21 U.S.C. § 360c(a)(1) (2012); Javitt, *supra* note 13, at 559.

require premarket approval because such devices are “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.”<sup>15</sup> Class III medical devices receive “the most federal oversight,” and include devices such as replacement heart valves, transvaginal surgical mesh, and pacemakers.<sup>16</sup> Overall, while the need for uniform and consistent federal regulation is necessary to ensure that safe and effective medical devices are readily available to consumers, the consequences imposed by the over-sweeping breadth of the MDA have significantly affected individuals’ ability to bring state-tort common law claims against negligent manufacturers of medical devices.

### A. Premarket Approval

Class III medical devices endure extensive review and require premarket approval before they may be introduced into the market.<sup>17</sup> Each manufacturer that submits a device for premarket approval must give the Food and Drug Administration (FDA) enough information to establish a “reasonable assurance” that each device is “both safe and effective.”<sup>18</sup> While premarket approval is deemed the gold standard for device safety and efficacy—for example, the majority of manufacturers undergo anywhere between nine and eighteen months, or longer, of testing and research<sup>19</sup>—it is not the only mechanism for approval of these devices. The 510(k) approval process is an alternative route for medical devices that “permits devices that are ‘substantially equivalent’ to pre-existing devices to avoid the [pre-market approval] process.”<sup>20</sup> However, the 510(k) process—which was

---

15. § 360c(a)(1)(C)(ii).

16. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008).

17. Class III medical devices go through a rigorous premarket approval process; the FDA spends an average of 1,200 hours reviewing each submission and determining the safety and efficacy of each device. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

18. *Lohr*, 518 U.S. at 477; see also U.S. FOOD AND DRUG ADMINISTRATION, MEDICAL DEVICES: DEVICE APPROVALS, DENIALS AND CLEARANCES (March 26, 2018), <https://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/default.htm> [<https://perma.cc/XJ8Z-X3V3>] (“A PMA is an application submitted to [the] FDA to request approval to market. Unlike premarket notification, PMA approval is to be based on a determination by [the] FDA that the PMA contains sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective for its intended use or uses.”).

19. See Barry Sall, *Regulation of Medical Devices*, in MADAME CURIE BIOSCIENCE DATABASE, available at <https://www.ncbi.nlm.nih.gov/books/NBK6534/>.

20. *Id.* at 478; see also § 360c(a)(1)(B).



essentially meant to be an “exception” to the PMA process<sup>21</sup>—has now seemingly become the norm.<sup>22</sup> While the 510(k) approval process is much more lax than the full premarket approval process, and although Congress recognizes that time and resources are a major limiting factor for the FDA with respect to giving each device full premarket approval, this fact cannot overshadow the importance of consumer safety. Therefore, in order to maintain the 510(k) approval process—and thus avoid the inevitable undue burden on the FDA—the FDA could actually enlist the states in a somewhat indirect way. Specifically, the use of state-tort liability might aid the FDA in incentivizing manufacturers to adequately research and test their products to ensure they meet the safety and efficacy standards required by the FDA, thus minimizing the potential of future tort lawsuits.<sup>23</sup>

### B. Class III Medical Devices and Preemption

As stated above, Class III medical devices present “a potential unreasonable risk of illness or injury” and are intended for life-saving or life-sustaining human use.<sup>24</sup> States must adhere to certain federal requirements that limit state regulations with respect to such medical devices. This arguably sparked controversy between the states and the federal government because, as noted above, medical devices were initially regulated by the states under the notion that “[s]tates traditionally . . . had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.”<sup>25</sup>

---

21. Statement of Dr. David A. Kessler, former FDA Commissioner, in *THE BLEEDING EDGE* (Netflix 2018); see also Alexandra Sifferlin, *What the Netflix Documentary ‘Bleeding Edge’ Gets Right About the Dangers of Medical Devices in America*, TIME (July 27, 2018), <http://time.com/5346330/what-the-netflix-documentary-bleeding-edge-gets-right-about-the-dangers-of-medical-devices-in-america/> [<https://perma.cc/7VR6-YSRA>].

22. See Jon Kamp & Thomas Burton, *How FDA Approved Hysterectomy Tools It Now Disfavors; Regulator Didn't Study Morcellator's Cancer Risk Until 18 Years After Approving for Gynecology*, WSJ (Dec. 16, 2014), <https://search.proquest.com/wallstreetjournal/docview/1636345453/5D6F17B3199B4180PQ/1?accountid=4840> (finding that in 2013, the 510(k) process was used to approve over 99 percent of the approximately 3,000 new device applications the FDA received in 2013).

23. See generally Elliot Sheppard Tarloff, Note, *Medical Devices and Preemption: A Defense of Parallel Claims Based on Violations of Non-Device Specific FDA Regulations*, 86 N.Y.U. L. REV. 1196 (2011). While this Author defends the “parallel claim,” as opposed to a “fraud-on-the-FDA” claim, the analysis can be applied to both in certain contexts, such as aiding the FDA in monitoring and redressing manufacturer malfeasance. See *id.* at 1226 (“[P]arallel claims based on violations of industry-wide FDA regulations are potentially less disruptive than fraud-on-the-agency claims.”). However, as argued throughout this Note, fraud-on-the-FDA claims may not be as “disruptive” as they are claimed to be.

24. § 360c(a)(1)(C)(ii).

25. *Lohr*, 518 U.S. at 475 (quoting *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985)); see also *Kubicki v. Medtronic, Inc.*, No. 12-cv-734 (KBJ), 2018 WL

Under the MDA, the federal requirements imposed on states are as follows:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.<sup>26</sup>

The first provision—the express preemption provision<sup>27</sup>—has contributed heavily to the conflict among courts across the country questioning whether state-tort common law claims can survive summary judgment.<sup>28</sup> While this provision is undoubtedly influential in shaping the preemption doctrine in this realm, the focus of this Note is on implied conflict preemption.

As a whole, the doctrine of preemption finds its strength in the principles set out in the Supremacy Clause of the United States

---

707428, at \*37 (D.C.C. Feb. 5, 2018) (“[T]his [c]ourt concludes that the [plaintiffs] claims against Medtronic that allege the negligent design, manufacture, and labeling of the [device] exist independently of the FDCA, and in fact, are precisely the type of claims that the *Lohr* Court anticipated would be allowed to proceed.” (citing *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 704 (S.D. Tex. 2014) (“[F]inding that state law fraud, negligence, and breach of warranty claims relating to medical device were not impliedly preempted where they ‘would exist in a world without the FDCA.’”))).

26. 21 U.S.C. § 360k(a) (2012).

27. Express preemption occurs when Congress has explicitly spoken to whether the federal statute’s intent is to preempt the competing or conflicting state law. *See Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008).

28. *See, e.g., McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1041 (9th Cir. 2015) (finding that “there is no suggestion that Congress intended to displace traditional tort law by making all policing of medical labels and warnings the exclusive province of the FDA,” and therefore holding that the plaintiff’s state-tort claims were not preempted by the MDA); *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010) (ruling that the plaintiff’s state law claims were neither expressly nor impliedly preempted by the MDA); *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145 (S.D.N.Y. 2011) (holding that the plaintiff’s failure to warn, failure to report, and negligence claims were preempted by the MDA); *Ilaraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009) (holding that because the plaintiff failed to allege any specific violation or noncompliance with FDA regulations that related to the plaintiff’s injury, her claims were preempted). Relatedly, prior to the holding in *Buckman*, some courts held that the now called “state-law fraud-on-the-FDA-claim” was expressly preempted by the MDA. *See Chadwell v. Optical Radiation Corp.*, 902 F. Supp. 830, 835 (S.D. Ind. 1995) (holding that the plaintiff’s claim of failing “to make truthful disclosures of material fact to the FDA” was preempted); *Kemp v. Pfizer Inc.*, 835 F. Supp. 1015, 1022 (E.D. Mich. 1993) (“Plaintiff has alleged that defendants engaged in a campaign of disinformation against the public and the FDA. Even if true, plaintiff’s state law claims are still preempted.”).

Constitution.<sup>29</sup> The Supremacy Clause places significant importance on the weight of federal law, and states have felt this pressure for years.<sup>30</sup> Of the two types of preemption, the pertinent discussion is on implied conflict preemption. Conflict preemption results from the “operation of the Supremacy Clause when federal and state law actually conflict, even when Congress says nothing about it.”<sup>31</sup> Further, conflict preemption “exists when ‘the state law makes it either impossible to follow the federal law or provides a significant obstacle to adhering to the federal law.’”<sup>32</sup> One thing to note though with implied conflict preemption is that courts should “begin with the assumption that a state law is valid and should be reluctant to resort to the Supremacy Clause.”<sup>33</sup> As courts have shown, however, this assertion is not necessarily followed.

Moreover, notwithstanding the “narrow gap” plaintiffs must maneuver to get through the MDA’s express preemption provision,<sup>34</sup> the long-standing notion of a presumption against preemption, with respect to traditional state-regulated domains, is currently being called into question.<sup>35</sup> While the Supreme Court’s jurisprudence seems somewhat hesitant when tasked with applying this presumption,<sup>36</sup> it

29. J. David Prince, *The Puzzle of Parallel Claims, Preemption, and Pleading the Particulars*, 39 WM. MITCHELL L. REV. 1034, 1037-38 (2013). The Supremacy Clause states, “[t]his Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” See U.S. CONST. art. VI, cl. 2.

30. See, e.g., *Arizona v. United States*, 567 U.S. 387, 416 (2012) (holding that due to the federal government’s long-standing history of regulating immigration within the United States, Arizona’s additional state laws, though similar in nature, undermine the goals and objectives of federal immigration law and are thus preempted); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 625-26 (2011) (holding that plaintiffs’ state-tort claims were preempted because it would be impossible for the drug manufacturer to comply with both state and federal law, which undermines the federal objectives of regulating pharmaceutical drugs).

31. *South Dakota R.R. Auth. v. Burlington N. & Santa Fe Ry. Co.*, 280 F. Supp. 2d 919, 927 (D.S.D. 2003).

32. *Martin v. Medtronic, Inc.*, No. 1:15-cv-00994, 2017 WL 825410, at \*3 (E.D. Cal. Feb. 24, 2017) (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)).

33. *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965 (6th Cir. 2004) (citation omitted).

34. See *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (“*Riegel* and *Buckman* create a narrow gap through which a plaintiff’s state-law claim must fit if it is to escape express or implied preemption.”).

35. See *Herron v. Smith & Nephew, Inc.*, 7 F. Supp. 3d 1043, 1047-48 (E.D. Cal. 2014) (noting the presumption against preemption, but nevertheless holding that the plaintiff’s state law claims were either expressly or impliedly preempted due to the presumption of Congress’ intent); see also *Riegel v. Medtronic Inc.*, 552 U.S. 312 (2008) (holding the plaintiff’s claims preempted, but never mentioning this presumption). But see *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (“[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action.”).

36. See Mary J. Davis, *The “New” Presumption Against Preemption*, 61 HASTINGS L.J. 1217, 1220 (2010) (“In the one hundred plus years that the Supreme Court has addressed

still remains integral to the underlying principles surrounding Tenth Amendment concerns of maintaining at least some regulation for states in areas where states traditionally operated. In situations such as this, where the federal government and the states both have legitimate interests in regulating a particular industry, implied preemption tends to lend its hand in favor of the federal government's interest. However, this presumption supporting preemption should not be so readily construed; instead, because the manufacturing of medical devices covers multiple dimensions of commerce and consumer health, the FDA should enlist these state-law claims to help carry out its delegated duties, or Congress could enact legislation combining its efforts with the states to aid in regulating this pervasive industry.

Thus, with the present frailty of the presumption against preemption, the question of whether state-tort common law claims can survive implied conflict preemption is ripe for debate. Courts have a duty to uphold this presumption because without it, federal law would undoubtedly exceed its permissible scope and intrude on the inherent authority of the states. Moreover, with regard to implied preemption, many courts have taken an expansive view, extending the boundaries to unimaginable ends. As noted above and discussed further below, *Buckman* significantly influenced this view, but many lower courts are now interpreting *Buckman* to apply to claims that should not be impliedly preempted. To an extent, although *Buckman* holds otherwise,<sup>37</sup> state-law fraud-on-the-FDA claims should not be impliedly preempted because there is no inherent conflict between the federal scheme and the numerous, complementary state-tort laws that are, or at least once were, in place.

Evidently, both mechanisms can work together to disincentivize manufacturers from attempting to submit potentially questionable medical devices for approval, thus allowing the FDA to focus on legitimately safe, carefully designed, and meticulously studied devices the public needs. If state law were paired with federal law in regulating the manufacturing and marketing of medical devices, the end result may include increased tort liability, which could inflate potential damages awarded to an injured plaintiff to enormous amounts, thus engendering and encouraging manufacturers to conduct strict, adequate, and reliable clinical studies before submitting devices for approval.<sup>38</sup> A manufacturer's duty of care under federal requirements

---

preemption issues, it has been inconsistent about the role that the presumption against preemption plays.”).

37. See *infra* Section II.C.

38. But see Mark Seidenfeld, *Who Decides Who Decides: Federal Regulatory Preemption of State Tort Law*, 65 N.Y.U. ANN. SURV. AM. L. 611, 623 (2010) (“[I]t is not clear how

combined with complementary and parallel state-tort liability would not add to or differ from such federal requirements, but would merely provide an extra incentive for manufacturers to remain transparent and accountable with the devices they seek to market to consumers.

### III. MANEUVERING THE LAW

For a plaintiff's state-tort common law claim to have a fighting chance of withstanding a preemption defense, the plaintiff must carefully craft the complaint to fit the pleading standard set out in *Twombly* and *Iqbal*,<sup>39</sup> as well as fit the mold of the narrow "parallel" claim set forth in *In re Medtronic Inc., Sprint Fidelis Leads*.<sup>40</sup> The trilogy of cases that highlight how, when, and to what extent a state-tort common law claim may survive a preemption defense is *Riegel v. Medtronic, Inc.*, *Medtronic, Inc. v. Lohr*, and *Buckman Co. v. Plaintiffs' Legal Committee*.<sup>41</sup> These cases intertwine with one another, playing piggy-back with the analysis of certain issues; however, *Buckman* is the only case in which the United States Supreme Court has ruled on implied preemption of state-law fraud-on-the-FDA claims.

#### A. Riegel

In *Riegel*, the plaintiff, Charles Riegel, received the Evergreen Balloon Catheter, which was a full premarket approved Class III device that was manufactured by the defendant, Medtronic, Inc.<sup>42</sup> After suffering an injury from the device, Riegel brought suit against Medtronic, alleging "that Medtronic's catheter was designed, labeled, and manufactured in a manner that violated New York common law, and that these defects caused Riegel to suffer severe and permanent injuries."<sup>43</sup> The Supreme Court affirmed the holding of the Second Circuit, barring Plaintiff's claims as preempted, stressing that:

---

strongly failure of regulation to prevent grossly inadequate care by a producer will correlate with a credible threat of a potentially ruinous tort suit.").

39. See *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) (holding the plaintiff need not plead specific facts to state a valid claim; the plaintiff must only plead enough facts to prove the claim is "plausible on its face"); *Ashcroft v. Iqbal*, 556 U.S. 662, 683 (2009) (holding that a claim must "nudge [the injury] across the line from conceivable to plausible" (quoting *Twombly*, 550 U.S. at 570)).

40. See *In re Medtronic Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205-08 (8th Cir. 2010).

41. *Riegel*, 552 U.S. 312; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Lohr*, 518 U.S. 470.

42. *Riegel*, 552 U.S. at 320.

43. *Id.*

State requirements are pre-empted under the MDA only to the extent that they are “different from, or in addition to” the requirements imposed by federal law. § 360k(a)(1). Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case “parallel,” rather than add to, federal requirements.<sup>44</sup>

*Riegel*’s impact on implied preemption, however, is relatively minimal.<sup>45</sup> *Riegel* concerns a full premarket approved Class III device, which suggests that if a Class III device undergoes full premarket approval, the ability for a plaintiff to bring state-tort common law claims against the manufacturer is very limited.<sup>46</sup> The main take-away from *Riegel* is the notion of the “parallel” claim that allows state-tort common law claims to potentially survive express preemption.<sup>47</sup> However, an issue arises when a parallel state-tort claim becomes subject to implied preemption, notwithstanding the fact that it prevailed against the express preemption clause.<sup>48</sup> In this situation, courts look to the complaint to determine its premise and if it tries to overstep the authority given to the FDA with respect to regulating medical devices.<sup>49</sup>

### B. Lohr

In *Medtronic, Inc. v. Lohr*, the plaintiff, Lora Lohr, was implanted with a pacemaker device, which received approval through the 510(k) process and was manufactured by the defendant, (again) Medtronic,

44. *Id.* at 330.

45. See Mark Hermann, David Booth Alden & Bradley W. Harrison, *The Meaning of the Parallel Requirements Exception Under Lohr and Riegel*, 65 N.Y.U. ANN. SURV. AM. L. 545, 561 (2010) (“[*Riegel*] said nothing about the extent to which [parallel] claims may be impliedly preempted.”).

46. See *Laverty v. Smith & Nephew, Inc.*, 197 F. Supp. 3d 1026, 1032 (N.D. Ill. 2016) (“Class III medical device manufacturers ‘who subject their Class III medical devices to the rigorous premarket approval process are protected by federal law from civil liability so long as they comply with federal law.’” (emphasis omitted) (quoting *Bausch v. Stryker Corp.*, 630 F.3d 546, 550 (7th Cir. 2010))); see also Demetria D. Frank-Jackson, *The Medical Device Federal Preemption Trilogy: Salvaging Due Process for Injured Patients*, 35 S. ILL. L.J. 453, 462 (2011) (“[P]remarket approved devices are subject to federal preemption protection.”).

47. See *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig.*, No. CCB-17-2775, 2018 WL 1471684, at \*7 (D. Md. Mar. 26, 2018) (“[A] plaintiff may succeed on her state law claim by proving conduct that violates federal requirements . . . that claim *parallels* federal requirements. The state law reliance on a federal regulation need not be explicit.” (emphasis added)).

48. See *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 872-73 (2000) (noting that, although “there is an ‘inference that an express pre-emption clause forecloses implied pre-emption,’” this does not extinguish the possibility of implied preemption ever applying in the face of an express preemption provision (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 289 (1995))).

49. See *Buckman*, 531 U.S. at 350.



Inc.<sup>50</sup> After implantation, the pacemaker failed, causing a “complete heart block” in Lohr that required her to undergo emergency surgery to fix the pacemaker.<sup>51</sup> Subsequently, Lohr filed suit against Medtronic, alleging negligence and strict liability claims.<sup>52</sup> The Supreme Court held that none of the plaintiff’s claims were preempted.<sup>53</sup> The Court reasoned that if Medtronic’s construction<sup>54</sup> of section 360k was upheld, medical device manufacturers would be granted “complete immunity from design defect liability,” and due to the industry’s reputation and operations, there is no possible or plausible reason that Congress “would, without comment, remove all means of judicial recourse for those injured by illegal conduct.”<sup>55</sup>

The major takeaway from *Lohr* with regard to Class III medical devices approved through the 510(k) process is “that pre-emption occur[s] only where a particular state requirement threatens to interfere with a specific federal interest.”<sup>56</sup> However, the effects of *Lohr* generated staggering inconsistencies with how lower courts interpret and decide whether express preemption is applicable in a given case.<sup>57</sup> With regard to implied preemption, however, the Court gave no indication or hint as to whether state law claims would be, or could be, impliedly preempted. This silence begs the question how state law claims that parallel, or even slightly add to, federal requirements *threaten* federal interests. If Congress’ overall objective in enacting the MDA was to increase the safety and regulation of medi-

---

50. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 480 (1996).

51. *Id.* at 481 (“According to her physician, a defect in the lead was the likely cause of the failure.”).

52. *Id.*

53. *Id.* at 503.

54. Medtronic argued that any state-tort common law cause of action is a state “requirement” that would explicitly violate the language of section 360k of 21 U.S.C.; therefore, “any and all common-law claims” should be preempted by the MDA. *Id.* at 486.

55. *Id.* at 487 (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)).

56. *Id.* at 500; see also Robert J. Katerberg, Note, *Patching the “Crazy Quilt” of Cipollone: A Divided Court Rethinks Federal Preemption of Products Liability in Medtronic, Inc. v. Lohr*, 75 N.C. L. REV. 1440, 1453 (1997) (“[I]n order for preemption to occur, the FDA regulation requires not only that the preempting FDA requirements be ‘specific counterpart regulations . . . applicable to a particular device,’ but also that the preempted state requirements not be ‘of general applicability.’” (footnote omitted) (citation omitted) (quoting FTC Credit Practices Rule, 21 C.F.R. § 808.1(d) (1996))).

57. Compare *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 776 (D. Minn. 2009) (holding that because, *inter alia*, the device is a Class III medical device that received full pre-market approval, thus setting out specific federal requirements for the device, the plaintiff’s claims were expressly preempted), with *Garross v. Medtronic, Inc.*, 77 F. Supp. 3d 809, 813, 815 (E.D. Wis. 2015) (holding that, notwithstanding the device being a Class III device that received full premarket approval, none of plaintiff’s state law claims were expressly preempted because they were all based on an “alleged underlying violation of federal law”).

cal devices, state-tort claims should improve this objective, not threaten it.<sup>58</sup> The end goal is the same for both means of regulation: to ensure medical devices are safe and that they achieve maximum consumer safety.

### C. Buckman

The focal point of this Note and the opinion that opened the door for widespread application of implied preemption barring state-tort common law claims is *Buckman Co. v. Plaintiffs' Legal Committee*.<sup>59</sup> In *Buckman*, the plaintiffs sustained spinal injuries from orthopedic bone screws placed in the pedicles of their spines.<sup>60</sup> The plaintiffs alleged that when the manufacturer of the bone screws submitted the screws for premarket approval, it made fraudulent representations to the FDA as to the device's intended use.<sup>61</sup> The Supreme Court held that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,'" and thus preemption is warranted because a state-law fraud-on-the-FDA claim inevitably conflicts with federal law.<sup>62</sup> The Supreme Court further stated:

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. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law.<sup>63</sup>

However, as pointed out by Justice Stevens in his concurrence, the majority's holding eliminates any and all potential remedies an injured consumer may seek against a fraudulent manufacturer.<sup>64</sup> Although the MDA are to be enforced solely by the federal government, there is no plausible argument that Congress envisioned these amendments to basically gift medical device manufacturers with

---

58. Particularly, if a state-tort claim alleges a manufacturer's breach of duty owed to a consumer—such as a state law requiring proper care in manufacturing medical devices—and this duty is not specifically owed to the FDA because it predates the MDA, the claim should not be impliedly preempted because it rests on traditionally state-regulated domains. *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017).

59. 531 U.S. 341 (2001).

60. *Id.* at 343.

61. *Id.* The bone screws received 510(k) approval. *Id.* at 346.

62. *Id.* at 347-48 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

63. *Buckman*, 531 U.S. at 348.

64. *See id.* at 355 (Stevens, J., concurring) ("Under the [Court's] pre-emption analysis . . . parties injured by fraudulent representations to federal agencies would have no remedy even if recognizing such a remedy would have no adverse consequences upon the operation or integrity of the regulatory process.").

complete immunity in tort suits.<sup>65</sup> Further, while “the FDCA provides the FDA ‘a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration,’ ”<sup>66</sup> as discussed below, state-tort fraud-on-the-FDA claims merely complement, rather than inhibit or impede, federal law in the regulation of medical devices. Thus, this suggested “variety of enforcement options” can be supplemented by state-tort law that is aimed at improving and enhancing the federal scheme as a whole for the sole purpose of protecting consumers.

Overall, *Buckman* bars any and all claims that attempt to question the “legitimacy of FDA actions.”<sup>67</sup> Arguably, though, state-tort claims that seek to ensure that manufacturers are being truthful to the FDA are not out to question the FDA’s practices and regulations; that is, plaintiffs, presumably, do not think the FDA is in the wrong. Rather, many claims simply try to uncover remedies for injuries caused by defective devices. Such claims also seek to improve consumer safety and assist the FDA in achieving its goals set out through the MDA by highlighting and remedying potential manufacturer fraud and dishonesty. If the FDA were to utilize such claims and impose this “second layer” of protection for the consumer—or rather, this additional incentive to the manufacturer to adequately study their products before submitting their application for approval—the FDA would have greater confidence that they are approving the safest and most efficacious devices for consumers.

#### D. Circuit Split

Circuits across the country face unparalleled uncertainty when tasked with determining whether federal law preempts parallel state-tort common law claims against medical device manufacturers of Class III medical devices.<sup>68</sup> The Court in *Buckman* even noted that

---

65. *Id.*; 2 JAMES T. O'REILLY & KATHARINE A. VAN TASSEL, FOOD AND DRUG ADMINISTRATION § 26:81, at 1 (4th ed. 2017).

66. JAMES T. O'REILLY & KATHARINE A. VAN TASSEL, FOOD AND DRUG ADMINISTRATION § 26:81, at 12 (4th ed. 2017) (quoting *Buckman*, 531 U.S. at 349).

67. James M. Beck, *Federal Preemption in FDA-Regulated Product-Liability Litigation: Where We Are and Where We Might Be Headed*, 32 HAMLINE L. REV. 657, 703 (2009).

68. See Jarett Sena, “*The Contours of the Parallel Claim Exception: The Supreme Court’s Opportunity to Define the Ill-defined*,” 42 FORD. URB. L.J. 291, 320 (2014) (“The Sixth and Eighth Circuits have adopted an expansive view of *Buckman* to impliedly preempt traditional state law tort claims premised on FDA violations. By contrast, the Fifth, Seventh, and Ninth Circuits have limited *Buckman*’s scope to fraud-on-the-FDA claims, thereby allowing traditional state law tort claims premised on FDA violations to avoid implied preemption.”); see also Jean Macchiaroli Eggen, *Navigating Between Scylla and Charybdis: Preemption of Medical Device “Parallel Claims*,” 9 J. HEALTH & BIOMEDICAL L. 159, 172 (2013) (“Although . . . courts often clearly set out the principles articulated by the Su-

their decision would “resolve a split among the Courts of Appeals” on the question of whether “fraud claims were . . . expressly [or] impliedly pre-empted.”<sup>69</sup> However, *Buckman* was decided in 2001 and *Riegel* was decided in 2008. As seen throughout this Note, many lower courts tried to figure out the state of the law between 2001 and 2008, and now, uncertainty remains as to the question of whether a plaintiff’s state law claim squeezes through the “narrow gap” created by *Riegel* and *Buckman*.<sup>70</sup>

### 1. *The Fifth, Seventh, and Ninth Circuits*

The Fifth, Seventh, and Ninth Circuits properly sustained the notion of a presumption against preemption, thus allowing plaintiffs to plead state-tort claims that might otherwise be subject to preemption.<sup>71</sup>

First, the Fifth Circuit in *Hughes v. Boston Scientific Corp.* held that the plaintiffs’ failure-to-warn claim was not preempted “to the extent that it [was] based on [the defendant’s] violation of applicable FDA regulations requiring accurate reporting of serious injuries and malfunctions of the . . . device.”<sup>72</sup> The court in *Hughes* also noted that implied preemption was not warranted because, unlike the plaintiffs in *Buckman*,<sup>73</sup> the plaintiffs here asserted a “recognized state tort claim,” which *Buckman* did not foreclose.<sup>74</sup>

---

preme Court, distinguishing express and implied preemption, their analyses are less clear.”).

69. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347 (2001).

70. *In re Medtronic Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010); see also Neil M. Issar, Note, *Preemption of State Law Claims Involving Medical Devices: Why Increasing Liability for Manufacturers is a Perilous but Pivotal Proposition*, 17 VAND. J. ENT. & TECH. L. 1085, 1094 (2015) (“Instead of narrowing the scope of *Buckman*’s implied preemption and *Riegel*’s express preemption, a circuit split has emerged regarding the narrow ‘gap’ through which a plaintiff’s claims can escape both implied and express preemption.”).

71. See *Sena*, *supra* note 68, at 320.

72. *Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 771 (5th Cir. 2011); see also *Bass v. Stryker Corp.*, 669 F.3d 501, 512 (5th Cir. 2012) (holding that if the plaintiff pleads that the manufacturer “failed to comply with either the [premarket approval requirements] or the CGMPs themselves and that this failure caused the injury, the plaintiff will have pleaded a parallel claim”). See *Sena*, *supra* note 68, at 318 (noting that the court in *Hughes* found that “the plaintiff’s state law failure-to-warn claim premised on [medical device reporting requirement] was not preempted”).

73. See *Buckman*, 531 U.S. at 347-49 (noting the plaintiffs here asserted a claim that rested solely on a violation of federal law, and without such federal regulations, the claim would not exist).

74. *Hughes*, 631 F.3d at 775; see also Eggen, *supra* note 68, at 186 (“The Fifth Circuit . . . distinguished [general failure-to-warn] claims from the ‘fraud-on-the-FDA’ claim asserted in *Buckman*, stating that the latter was “a freestanding federal cause of action.”).

Next, the Seventh Circuit in *Bausch v. Stryker Corp.* held, *inter alia*, that the plaintiffs' state law claims were neither expressly nor impliedly preempted so long as they rested on a violation of federal law.<sup>75</sup> Further, *Bausch* laid out the foundation for the proposition that a plaintiff's claim need only allege a manufacturer's violation of federal law.<sup>76</sup> Consequently, a state-tort fraud-on-the-FDA claim—that is, a blatant violation of federal law—would survive implied preemption as well.

Finally, the Ninth Circuit in *Stengel v. Medtronic, Inc.* held that the MDA did not preempt the plaintiffs' state law failure-to-warn claim “insofar as the state-law duty parallels a federal-law duty under the MDA.”<sup>77</sup> The Court noted that even if the standard for a parallel claim were more precise in this situation, the plaintiffs' claim would still survive because the applicable state law “contemplates a warning to a third party such as the FDA,”<sup>78</sup> and the plaintiffs alleged that the manufacturer failed to warn the FDA of adverse events.<sup>79</sup>

Overall, these three circuits have set the stage for upholding the presumption against preemption—which is currently begging for a life raft. All of these circuits heed the suggestion that state-tort common law claims that parallel federal law will survive both express and implied preemption, even if the state-tort claim rests on a manufacturer's breach of a duty owed to the plaintiff to be truthful and transparent.<sup>80</sup> Presumably, these three circuits might also heed the suggestion that fraud-on-the-FDA claims do not necessarily conflict with federal law, but rather complement it to a degree that only boosts the efficiency of the FDA as a whole in regulating and policing fraud.<sup>81</sup>

---

75. *Bausch v. Stryker Corp.*, 630 F.3d 546, 556, 558 (7th Cir. 2010). *But see* McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005) (holding that the plaintiff's claim for post-sale failure to warn was preempted because section 814.39 of 21 C.F.R. does not require a manufacturer to provide “interim supplemental warnings pending approval by the FDA,” thus the claim added “additional” requirements and was preempted); *see also* *Sena*, *supra* note 68, at 326.

76. *Bausch*, 630 F.3d at 552-53, 559.

77. *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013).

78. *Id.*

79. *Id.* at 1226; *see also* *Sena*, *supra* note 68, at 326-27.

80. David G. Owen, *Federal Preemption of Products Liability Claims*, 55 S.C. L. REV. 411, 434 (2004).

81. *See, e.g.*, *Sena*, *supra* note 68, at 352 (“Another reason to attach the presumption against preemption is the need for state-law claims to complement FDA enforcement actions. . . . [S]tate-law tort claims are needed to make up for the deficiencies in the FDA post-market surveillance process.”); Tarloff, *supra* note 23, at 1224 (“Parallel claims based on violations of the FDA's industry-wide regulations can complement the FDA's efforts in all of [their] endeavors.”).

## 2. *The Sixth and Eighth Circuits*

On the other end of the spectrum, the Sixth and Eighth Circuits have staunchly overemphasized the authority of the MDA's express preemption provision<sup>82</sup> and the scope of implied preemption.<sup>83</sup> Both of these circuits have ruled in favor of sustaining, and arguably expanding, the scope and force of federal preemption in this realm. For instance, the Sixth Circuit in *Kemp v. Medtronic, Inc.* held that "permitting a fraud claim premised on false representations to the FDA during the [premarket approval] process would conflict with well-established precedent that no implied private right of action exists under the FDCA."<sup>84</sup> However, this analysis seems misplaced; a claim premised on false representations to the FDA during the premarket approval process does not create a private cause of action, but rather it highlights a manufacturer's violation of the federal requirements—usually found in the Code of Federal Regulations—imposed under the premarket approval process, which the federal government seeks to police. The Sixth Circuit maintained this broad scope of implied preemption in *Cupek v. Medtronic, Inc.*<sup>85</sup> Here, the court preempted, *inter alia*, the plaintiffs' state law "post-sale 'failure to warn' " claim,<sup>86</sup> holding that the plaintiffs' assertion that the defendants had "duties 'independent of any obligations . . . to comply with applicable federal requirements,' " were still " 'in addition to' [or even different from] federal requirements," and were thus preempted.<sup>87</sup> In *Cupek*, the "additional" duties involved manufacturers reporting updated information regarding a specific device to the FDA, which a manufacturer is required to do under federal law.<sup>88</sup> As stated throughout, this

---

82. 21 U.S.C. § 360k(a) (2012).

83. See *Sena*, *supra* note 68, at 320 ("The Sixth and Eighth Circuits have adopted an expansive view of *Buckman* to impliedly preempt traditional state law tort claims premised on FDA violations.").

84. *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236 (6th Cir. 2000); see also 21 U.S.C. § 337(a) (2012). The MDA provides that "all actions to enforce FDA requirements 'shall be by and in the name of the United States.' " *In re Medtronic Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting 21 U.S.C. § 337(a)); cf. *Howard v. Sulzer Orthopedics, Inc.*, 382 Fed App'x 436 (6th Cir. 2010). In *Howard*, the Sixth Circuit was faced with deciding whether state requirements of a medical device paralleled federal requirements, specifically the "Current Good Manufacturing Practices." *Id.* at 439. While this case does not concern a private right of action or false misrepresentations, the court nonetheless held that "if the FDA may require a manufacturer to keep a device oil-free [the issue in the case], a state may provide a damages remedy for violations of an identical state requirement." *Id.* at 441. This lends support to not only claims overcoming express preemption, but implied preemption as well.

85. 405 F.3d 421 (6th Cir. 2005).

86. *Id.* at 422.

87. *Id.* at 425.

88. See *id.* at 424.



scheme should be viewed as a mechanism to support federal law, not as a hindrance or obstacle to it. While these state laws might be viewed as “double-dipping” in tort law, thus chilling innovation and deterring the creation of potentially life-saving devices, one cannot disagree that this scheme could serve as an incentive to manufacturers to expend appropriate resources to adequately research and test these devices before sending them to market.

Additionally, the Eighth Circuit in *In re Medtronic, Inc., Sprint Fidelis Leads* held that all of the plaintiffs’ claims were preempted,<sup>89</sup> either due to a failure to plead a parallel claim or due to the prohibition of private parties attempting to enforce the MDA.<sup>90</sup> The court focused on the fact that the plaintiffs pled claims that amounted to “a frontal assault on the FDA’s decision to approve a [premarket approval] Supplement after weighing the product’s benefits against its inherent risks.”<sup>91</sup> However, similar to *Kemp*, where the Sixth Circuit misplaced its focus on one’s inability to bring a private right of action, the Eighth Circuit failed to analyze the plaintiffs’ claims outside of the *Riegel* framework, essentially affirming the notion that medical device manufacturers can escape liability if their products obtain full premarket approval.<sup>92</sup>

These decisions are perverse to the whole notion of tort liability; manufacturers in many industries—particularly, manufacturers of medical devices—have the potential to produce intrinsically dangerous products, and the idea that they could receive judicial immunity from potential lawsuits simply because their products went through the FDA’s most stringent approval process—the premarket approval process—is threatening to both the regulatory scheme and to the remedies available for consumers who are genuinely harmed by medical devices.<sup>93</sup> Additionally, it should be noted that this analysis—that of the Sixth and Eighth Circuits—concerns cases involving devic-

---

89. See Tarloff, *supra* note 23, at 1211 (“[T]he court . . . found all of the Sprint Fidelis plaintiffs’ claims either expressly or impliedly preempted.”).

90. *In re Medtronic Inc., Sprint Fidelis Leads*, 623 F.3d at 1205-07.

91. *Id.* at 1207.

92. Issar, *supra* note 70, at 1099; see also *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 333 (2008) (Ginsberg, J., dissenting) (arguing that the Court’s interpretation of the MDA pardons medical device manufacturers from liability “once the application for the design or label has gained premarket approval from the [FDA]”); see Charles Warren, *When the Feds Have Taken the Field: Federal Field Preemption of Claims Against Manufacturers Whose Medical Devices Have Received Premarket Approval by the FDA*, 9 OKLA. J. L. & TECH. 65 (2013) (“Viewed from the [Sixth Circuit’s] perspective, when a device passes the FDA’s rigorous PMA standards, it reaches the pinnacle of what may be required of it in terms of safety.”).

93. See Issar, *supra* note 70, at 1099 (“Such unqualified immunity for manufacturers is improper in the medical device context; medical devices are inherently risky and no approval process can guarantee perfect safety.”).

es that obtained full premarket approval; the current state of the less-intensive 510(k) approval process is foggy,<sup>94</sup> but precedent suggests that devices approved through this process are more susceptible to state-tort liability.<sup>95</sup> While the express preemption provision applies to both full premarket approved medical devices and devices approved through the 510(k) process,<sup>96</sup> after *Buckman*, courts have been inconsistent in determining whether implied preemption applies equally to both as well. The cases discussed above do not elaborate on the implications of implied preemption as applied to 510(k)-approved devices.<sup>97</sup>

Further, neither of these circuits ventured to analyze or explain the impact of implied preemption on parallel state-tort common law claims.<sup>98</sup> *Buckman* failed to address this issue as well,<sup>99</sup> and it seems that some courts are taking this silence as approval to apply implied preemption on parallel state-tort claims, especially failure-to-warn and fraud-like claims.<sup>100</sup> However, this assumption may be misplaced.

94. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); see also *supra* Part II.

95. *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); *McClellan v. I-Flow Corp.*, 776 F.3d 1035 (9th Cir. 2015); see also *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1245 (7th Cir. 1997) (holding that the state-tort claim of negligence brought against a device approved through the FDA's less rigorous process, known as the "investigational device exemption," was not expressly or impliedly preempted).

96. Joyce B. Margace & Michelle R. Scheiffele, *Is the Preemption Defense for PMA-Approved Medical Devices in Jeopardy?*, 75 DEF. COUNS. J. 12, 14 (2008) ("The express preemption provision applies to devices that enter the market through both the [premarket approval] and § 510(k) processes.").

97. *In re Medtronic Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000).

98. See *In re Medtronic, Inc., Sprint Fidelis Leads*, 623 F.3d at 1204-07; *Kemp*, 231 F.3d at 222 (noting that where Congress has explicitly spoken to the precise question at issue, like the express preemption provision in the MDA, the court has no reason to consider implied preemption).

99. One commentator noted that if *Buckman* did in fact concern a full premarket approved device, then "fraud-on-the-FDA claims [would] appear to be parallel requirements claims under *Lohr* and *Riegel*. They would 'provide a traditional damages remedy for violations of common-law duties [that] parallel federal requirements,' namely the federal requirements that require manufacturers to provide the FDA with truthful and complete data when seeking PMA approval." See Hermann et al., *supra* note 45, at 570 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

100. See, e.g., *Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1174 (S.D. Cal. 2016) (holding that although the FDA did not consider a particular risk associated with the medical device when evaluating the device's warning, that fact does not bar the court from applying implied (conflict) preemption to the plaintiff's claims); *Enlow v. St. Jude Med., Inc.*, 210 F. Supp. 2d 853, 860 (W.D. Ky. 2001) (holding that the plaintiff's failure-to-warn claim was preempted "to the extent that . . . [the] claim is premised on the adequacy of the warnings reviewed and approved by the FDA"); see also *Sena*, *supra* note 68, at 321 ("Like the Sixth and Eighth Circuits, various district courts have expanded *Buckman* beyond fraud-on-the FDA to impliedly preempt traditional state law tort claims.").

Silence does not equal permission, and the consequences stemming from courts that take this silence as permission could prove to be detrimental to state-tort liability.

#### IV. THE RELATIONSHIP BETWEEN THE FDA AND STATE-TORT CLAIMS

At first glance, the relationship between the FDA and state-tort claims would tend to cast doubt on the presumption against preemption due to the agency's regulatory scheme and its protections as applied to manufacturers. This doubt can be overcome, however, if the FDA were to use such claims to its advantage. With regard to the issue of implied conflict preemption and the arguments in favor of expanding the scope and use of implied preemption in the context of medical devices, it should be noted that state-tort common law claims do not actually hinder or conflict with the federal scheme that regulates medical devices. Regardless of whether a particular device received full premarket approval or approval through the 510(k) process, "fraud-on-the-FDA" claims only aim to improve the federal scheme and maintain transparency between the manufacturer and the consumer. Arguably, state-tort claims that "[p]olic[e] fraud against federal agencies" seek to monitor the manufacturer itself, not the agency.<sup>101</sup> Therefore, *Buckman* and its progeny misunderstand the relationship between the FDA and state-tort common law claims brought by injured plaintiffs seeking recourse. For example, in *In re Medtronic, Inc., Implantable Defibrillators Litigation*,<sup>102</sup> the court noted:

[A] manufacturer's knowing failure to disclose its own positive knowledge of danger hidden in an approved medical device has its own effect: the company's failure to exhibit absolute probity could be found to have knowingly deprived the FDA of information needed to confer its approval for the device to be implanted in humans.<sup>103</sup>

Thus, in order to allow the FDA to strongly incentivize manufacturers against participating in deceptive practices and techniques, state-tort law can serve as a second line of defense to aid the FDA in identifying and deterring manufacturer malfeasance.

With multiple arguments supporting the position that state-tort liability must acquiesce to federal law and regulation,<sup>104</sup> it should be emphasized that consumer protection is the FDA's first priority:

---

101. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001).

102. *In re Medtronic, Inc., Implantable Defibrillators Litig.* 465 F. Supp. 2d 886 (D. Minn. 2006).

103. *Id.* at 900-01.

104. Proponents of preemption of state-tort claims argue that claims similar to "fraud-on-the-FDA" would impose undue burdens on medical device manufacturers and the FDA

FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection. FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. Regulation cannot protect against all possible injuries that might result from use of a device over time. Preemption of all such claims would result in the loss of a significant layer of consumer protection, leaving consumers without a remedy for injuries caused by defective medical devices.<sup>105</sup>

This highlights the concern expressed by Justice Ginsberg's dissent in *Riegel* and Justice Blackmun's dissent in *Silkwood v. Kerr-McGee Corp.* that "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."<sup>106</sup> This is another justification for the assertion that state-tort fraud-on-the-FDA claims complement, rather than impede or conflict with, federal law. It is actually difficult to see how "conflicting" state requirements—such as requirements of a warning label or requirements involving continued reporting on the device to the FDA, would hinder or impede a federal law from achieving its objectives. It is easier to see how it might be difficult (and impractical) for a manufacturer to try to draft a warning label to fit all fifty states' requirements, but this is exactly why the federal government should step in to create a federal requirement that respects differing state laws and attempts to reconcile them into a coherent, universally known, and consistently applied labeling requirement. As stated above,<sup>107</sup> such state requirements—which essentially require the same conduct from the manufacturer as federal law—might better incentivize manufacturers to adequately research and test a device before submitting its application to the FDA. This "side-kick"<sup>108</sup> state law would, in essence, assist the FDA in policing potential malfeasance or fraud on the part of the manufacturer.

---

itself because such claims would incentivize "manufacturers to submit documents to avoid fraud-on-the-FDA liability . . . during the premarket approval process," and these claims would significantly impede the agency's ability to get beneficial products on the market by subjecting it to "the discovery process." See Tarloff, *supra* note 23, at 1226-27.

105. Margaret Jane Porter, *The Lohr Decisions: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 11 (1997).

106. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 266 (1984) (Blackmun, J., dissenting) (quoting another source); see also *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 337 (2008) (Ginsberg, J., dissenting); see, e.g., Sena, *supra* note 68, at 349; *supra* note 55 and accompanying text.

107. See *supra* text accompanying note 88.

108. I use the term "side-kick" to denote a Batman-and-Robin-type relationship, with Batman exemplifying federal law and Robin exemplifying state law.

Additionally, state-tort fraud-on-the-FDA claims can be construed as claims that rest on both traditional state law and federal regulations. While *Buckman* clarifies that claims cannot rest solely on federal law,<sup>109</sup> these state-law fraud-on-the-FDA claims arguably rest on both federal law and traditional state-tort law. Manufacturers have always had a duty to be honest and transparent with whatever entity governs it, whether it is the traditional state law that governed before the enactment of the MDA or federal regulations imposed by the FDA.<sup>110</sup> As such, regardless of which body authoritatively regulates medical device manufacturers, these fraud-on-the-FDA claims find their roots in both state and federal law. For example, a plaintiff brings a claim against a manufacturer alleging that the manufacturer failed to conform to the standards governing its operations by submitting allegedly fraudulent information to the FDA.<sup>111</sup> This type of claim rests on the federal regulations governing how manufacturers must comply with the FDA's regulatory and reporting standards. This claim may also rest on the state-tort law of negligence for failing to take reasonable care in studying the device and submitting accurate information for approval. Thus, if courts are to follow *Buckman's* analysis, the injured consumer would have no available avenues for recourse and the manufacturer would likely get off scot-free and act with impunity. This result would seem counterintuitive to the intent behind not only the MDA but the preapproval process as well.

Furthermore, although federal preemption has a valid and legitimate place in numerous areas of governmental regulation—such as immigration—federal preemption of state-tort common law claims against medical device manufacturers should not be so robust that it impossibly limits consumers from pleading claims after an incurring an actual injury-in-fact. This is not to say that federal preemption in this realm should not exist; rather, it should not be as pervasive. An analysis of the differences between these two areas of regulation might provide useful reasoning and justification for the assertion that federal preemption should not be as wide-sweeping as it currently is with medical devices.

With regard to immigration, *Arizona v. United States* gives a particularly definitive explanation of why federal preemption is necessary in this realm. In *Arizona*, the State of Arizona enacted a statute

---

109. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001).

110. See 21 C.F.R. § 814.45 (2017) (“[The] FDA may deny approval of a [premarket approved device] . . . [if] [t]he [premarket approval application] contains a false statement of material fact.”); *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455, 460 (4th Cir. 1960) (“[T]he [FDCA] imposes an absolute duty on manufacturers not to misbrand their products [in this case a surgical nail], and the breach of this duty may give rise to civil liability.”).

111. See, e.g., 21 C.F.R. 814.20 (2017); 21 C.F.R. 803.10 (2017).

to address the issue of illegal aliens within the state.<sup>112</sup> This statute aimed to “discourage and deter the unlawful entry and presence of aliens and economic activity by persons unlawfully present in the United States.”<sup>113</sup> The question presented to the Supreme Court was whether federal law preempts multiple provisions of Arizona’s statute.<sup>114</sup> The Court held that three of the provisions at issue were preempted, and the Court reasoned, *inter alia*, that the federal government “has significant power to regulate immigration,” and although “Arizona may have understandable frustrations with the problems caused by illegal immigration . . . the State may not pursue policies that undermine federal law.”<sup>115</sup> Thus, Arizona’s statute that gave state officers the power and authority to “decide whether an alien should be detained for being removable . . . violates the principle that the removal process is entrusted to the discretion of the Federal Government.”<sup>116</sup>

The decision in *Arizona* on implied preemption is analogous to the regulation of medical devices in that the Supreme Court held in both situations that state law that protrudes into the realm of federal regulation and either impedes or has the potential to impede the federal scheme will be preempted. However, immigration, which has traditionally been regulated by the federal government, is an incredibly broad and national issue that expands across multiple levels of policy, including domestic and foreign relations. Medical devices, on the other hand, were traditionally regulated by the states.<sup>117</sup> This fact warrants deference and respect to state-tort common law claims when such claims share the same goal and purpose as federal law, notwithstanding the fact that these devices are marketed and sold both nationally and globally. The strongest argument in favor of allowing state assistance to medical device regulation is that it does not seem likely that the federal scheme will encounter hindrances or impediments by enforcing and recognizing state-tort fraud-on-the-FDA claims. The federal regulatory scheme does not lose its power or credibility if state-tort liability serves as a companion to the FDA’s authority to police fraud and tortious misconduct. If anything, such additional and complementary police power would enhance the FDA’s function and operation by allowing the FDA to use its limited time

---

112. *Arizona v. United States*, 567 U.S. 387, 392-3 (2012).

113. *Id.* at 393 (quoting ARIZ. REV. STAT. ANN. § 11-1051 n. (2012)).

114. *Id.*

115. *Id.* at 416; The Court also noted that “[b]y . . . authorizing state and local officers to engage in . . . enforcement activities as a general matter, [the statute] creates an obstacle to the full purposes and objectives of Congress.” *Id.* at 410.

116. *Id.* at 409.

117. *See supra* note 25 and accompanying text.



and resources more efficiently at the premarket approval stage, rather than utilizing such resources after a device has been approved. Presumably, fraud is more likely to present itself at the premarket approval stage because manufacturers want to start selling their products quickly.

For example, if an injured plaintiff discovered evidence of a medical device manufacturer's misrepresentations to the FDA regarding either preapproval or post-approval studies and reports, but the state in which the plaintiff brought suit did not have a "parallel" requirement for her claim to stand on, the manufacturer would essentially escape liability if the FDA either did not credit the discovered evidence or did not believe the evidence would affect the approval status of the device in question. (The latter seems more likely to be the case.) This is where state-tort fraud-on-the-FDA claims would step in and aid the federal scheme of policing fraud and ensuring that medical device manufacturers create the safest and most effective devices available to the public. Such claims do not add to or differ from<sup>118</sup> the federal scheme, and they do not inherently conflict with federal regulations; they actually enhance the system in such a way that allows the FDA to accurately and confidently identify and address manufacturer malfeasance, while still maintaining the necessary autonomy for manufacturers to design, study, and market innovative medical devices.

The Court in *Buckman*, along with many lower courts, seemed to believe that fraud-on-the-FDA claims target the FDA itself and its alleged failure to uncover manufacturer wrongdoing.<sup>119</sup> However, this may not be the case with such claims. These state-law claims, similar to negligent misrepresentation and fraud claims, target the manufacturer and its allegedly unlawful conduct. The end goal is not to punish or chide the FDA; it is to uncover manufacturer wrongdoings and assist the FDA in addressing and remedying such wrongdoings in the aftermath of consumer injury. While negligent misrepresentation and fraud claims generally rest on traditional state law, irrespective of the FDCA,<sup>120</sup> state-law fraud-on-the-FDA claims hold identical purposes and should not be disallowed due to their perceived status as allowing a private right of action against the FDA. While the MDA does not offer or permit a private right of action, this is not the case with fraud-on-the-FDA claims. Such claims arise from the manufac-

---

118. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

119. *See supra* notes 62-63 & 66 and accompanying text.

120. *See Eidson v. Medtronic, Inc.*, 40 F. Supp. 3d 1202, 1227 (N.D. Cal. 2014) (holding that the plaintiff's negligent misrepresentation and fraudulent misrepresentation claims were not impliedly preempted because they "exist independently" from the FDCA).

turer's duty owed to the consumer when it submits a device for approval to the FDA.<sup>121</sup> This duty encompasses the assurance that, if approved and offered to consumers, the device is safe, efficacious, and tirelessly studied. Therefore, such claims could arguably stand on any independent state law involving a manufacturer's basic duty of care. However, even if these claims cannot find support in traditional state-tort law, the fact that these claims rest solely on federal law should not preclude the consumer from at least bringing sufficient evidence of potential manufacturer malfeasance to the FDA for them to investigate.

Nevertheless, in light of this vexed position, the Supreme Court's holding in *Buckman* made this argument susceptible to attack on the grounds that only the FDA itself has the authority to determine how it will handle issues of fraud and any attempt to aid that authority is an encroachment on the Agency.<sup>122</sup> *Buckman* furthers the notion that the balance of statutory objectives that the FDA seeks to achieve "can be skewed by allowing fraud-on-the-FDA claims under state tort law."<sup>123</sup> The Court also emphasized the potential undue burden placed on medical device manufacturers if state-law fraud-on-the-FDA claims were to succeed; specifically, the Court feared the chilling effect on "off-label" use of medical devices and the influx of potentially unnecessary information that manufacturers would give to the FDA.<sup>124</sup> *Buckman* also classified fraud-on-the-FDA claims as "freestanding federal cause[s] of action based on violation[s] of the FDA's regulations," not traditional state-tort duties.<sup>125</sup> Thus, *Buckman* aids in understanding the "narrow gap" a plaintiff must plead for a state-tort claim to survive.<sup>126</sup>

However, as discussed above, such claims should not be analyzed as resting solely on violations of federal requirements, thus serving as a private right of action. Rather, fraud-on-the-FDA claims should be interpreted as complementary authoritative agents that assist the FDA in ensuring manufacturers remain honest and produce safe and effective medical devices. With a similar mindset, the Ninth Circuit in *Stengel* held that the state (Arizona) recognized a duty placed on

---

121. See *supra* Section II.D.1.

122. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

123. *Id.*

124. *Id.* at 350; see Issar, *supra* note 70, at 1113 (noting that proponents of federal preemption argue that tort law "over-deter[s] manufacturers" by adding a layer of cautionary discretion concerning the creation of new medical devices that consumers actually need).

125. *Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 775 (5th Cir. 2011); *Buckman*, 531 U.S. at 353.

126. See *supra* Part I.

manufacturers to warn third parties of known adverse events, as well as those that reasonably should be known.<sup>127</sup> *Stengel* noted that “[u]nder Arizona law, a warning to a third party satisfies a manufacturer’s duty if, given the nature of the warning and the relationship of the third party, there is ‘reasonable assurance that the information will reach those whose safety depends on their having it.’ ”<sup>128</sup>

Therefore, the argument presented here is that a state-tort common law claim of fraud-on-the-FDA does not usurp the power of the FDA or the federal government by giving a plaintiff a private right of action. Rather, such claims stem from the overarching desire of both state and federal law to ensure the safety and efficacy of medical devices and to ensure that medical device manufacturers comply with complementary and parallel laws. As noted by one commentator, “parallel claims based on violations of FDA industry-wide requirements, far from interfering with the FDA’s enforcement decision making, should strengthen the FDA’s position.”<sup>129</sup> Engaging in this viewpoint—notwithstanding its sole focus resting on parallel claims instead of fraud-on-the-FDA claims—it would seem obvious that the FDA, by recruiting state-tort law (either recognizing parallel claims, fraud-on-the-FDA claims, or both), could maximize its capabilities in regulating this industry while serving the interests of the consumer.

Additionally, the Seventh Circuit in *Bausch* provides a similar analysis of state-tort claims that do not necessarily rest on explicit state law but still warrant attention.<sup>130</sup> The Seventh Circuit was tasked with deciding whether a medical device alleged to be “adulterated” was impliedly preempted because “no state tort duty to manufacture a product that is not adulterated” existed.<sup>131</sup> The Court held:

The MDA defines an “adulterated” device as a device “not in conformity with applicable requirements or conditions.” 21 U.S.C. § 351(h). 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

---

127. See *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (“Arizona law contemplates a warning to a third party such as the FDA.”).

128. *Id.* (quoting *Anguiano v. E.I. DuPont de Nemours & Co.*, 808 F. Supp. 719, 723 (D. Ariz. 1992)). But see *Littlebear v. Advanced Bionics, LLC*, 896 F. Supp. 2d 1085, 1092 (N.D. Okla. 2012) (holding that “adverse event reporting requirements are not substantive safety requirements under state law, but rather administrative requirements”).

129. See Tarloff, *supra* note 23, at 1225.

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

131. *Id.*

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.<sup>132</sup>

This reasoning suggests that some courts may be persuaded by arguments in favor of state-tort liability, notwithstanding the absence of a foundation resting on traditional state-tort law.

While the arguments against allowing such claims are valid, as *Buckman* highlights, they do not reach the level of concern that warrants the disabling of state-tort claims. David A. Kessler<sup>133</sup> and David C. Vladeck<sup>134</sup> proffered their opinions on the strength of the FDA's regulatory regime, concluding that "the FDA's efforts to restrict or eliminate the complementary discipline placed on the market by failure-to-warn litigation" are highly questionable.<sup>135</sup> They further explain that "the FDA is wrong to focus on the moment of approval as determinative of the preemption question. . . . [Because] [a]t the time of approval, the FDA's knowledge-base . . . is . . . highly limited because, at that point, the drug has been tested on a relatively small population of patients."<sup>136</sup> Finally, Kessler and Vladeck contend that "the tort system has historically provided important information about . . . [post-approval] risks to physicians, patients, and the FDA."<sup>137</sup> With this as a backdrop, fraud-on-the FDA claims do not inherently conflict with federal law, nor do they "hijack the FDA's enforcement decisions."<sup>138</sup> Such claims—though premised entirely on the existence of federal requirements, thus lacking a foundation root-

---

132. *Id.*

133. David A. Kessler was the Commissioner of the FDA from 1990 to 1997. See David A. Kessler, M.D., U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/History/FOrgsHistory/Leaders/ucm093724.htm> (last visited Sept. 27, 2018) [<https://perma.cc/FA7K-7BB2>].

134. David C. Vladeck was the Director of the Federal Trade Commission's Bureau of Consumer Protection from 2009 to 2012. See David C. Vladeck, GEORGETOWN LAW, <https://www.law.georgetown.edu/faculty/david-vladeck/> [<https://perma.cc/JK53-SX34>].

135. David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 465 (2008). Kessler and Vladeck's article examined the FDA's role in regulating pharmaceutical drugs, but the analysis can be applied almost identically to medical devices due to the similarities in their regulatory schemes. See also Issar, *supra* note 70, at 1113 ("[R]ecent history suggests that the FDA does not have adequate time, capacity, or resources to monitor manufacturers to ensure that their post-market conduct complies with safety requirements; to perform the necessary cost-benefit analysis to determine when enforcement actions are appropriate; or to pursue legal actions against manufacturers when doing so would be efficient.").

136. Kessler & Vladeck, *supra* note 134, at 465-66.

137. *Id.* at 466; see also Tarloff, *supra* note 23, at 1225-26 ("Private litigation against manufacturers brings an inflow of private capital from litigants and results in information disclosures through the discovery process. These features of private litigation have led many to describe the tort system as a critical 'catalyst' for public enforcement." (footnotes omitted) (quoting Bates v. Dow Agrosiences LLC, 544 U.S. 431, 451 (2005))).

138. Tarloff, *supra* note 23, at 1228.

ed in state-tort law—possess the same purposes of traditional state-tort law and would, as stated above, allow the FDA to focus its resources and utilize them more efficiently in the premarket approval process.

Furthermore, these types of claims do not “hijack” any decisions authoritatively given to the FDA because they encompass the same types of decisions the FDA would make regardless. If the FDA knew of any fraudulent practices by a manufacturer, it would presumably seek to enjoin the manufacturer from continuing such practices and take the necessary steps to ameliorate any negative impacts stemming from the manufacturer’s fraud, which should inherently include allowing an injured plaintiff to seek recourse. Allowing state-tort fraud-on-the-FDA claims to survive preemption would not impose requirements “different from, or in addition to”<sup>139</sup> federal requirements, nor would it detract from the federal scheme of regulating medical device manufacturers. Instead, it would only enhance the system as a whole and incentivize manufacturers to create safe and beneficial products expediently, with the added incentive of ensuring that premarket and post-approval studies and reports are honest, timely, and equitable to both the FDA and the consumer.

## V. CONCLUSION

It is of no doubt that medical device manufacturers have crafted and marketed vital, necessary, and life-saving devices that the public needs. However, due to the inherent volatile nature of courts’ interpretations of the MDA, it seems an opportune time for the Supreme Court to inject itself into this discussion once again to smooth out the wrinkles that are present within this doctrine and jurisprudence. Medical device regulation needs uniform application and consistency in its analytical framework. With states previously controlling such regulation, deference and credence should be afforded to state-tort laws that parallel federal law, and state-tort laws that complement the federal scheme by serving its interest in a parallel way, such as fraud-on-the-FDA claims. Thus, courts should find that state-law fraud-on-the-FDA claims are not impliedly preempted because they do not inhibit the federal scheme, nor do they commandeer the police power of the FDA.

---

139. 21 U.S.C. § 360k(a)(1) (2012).

