PREEMPTION AFTER *BUCKMAN*: STATE LAW FAILURE TO WARN CLAIMS BASED ON LACK OF DISCLOSURE TO THE FDA

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INTRODUCTION

Amidst cries for tort reform[1] and the ongoing "preemption war" that has taken the courts by storm,[2] an atmosphere of unease has settled over the American public regarding the rise of the administrative state and the expansive power of federal bureaucracies.[3] The subject of intense controversy, the scope of administrative agency control stretches beyond abstract theoretical and political debate, generating practical ramifications against the backdrop of a shocking increase in medical device injuries over

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1. *See generally* CONG. BUDGET OFF., THE EFFECTS OF TORT REFORM: EVIDENCE FROM THE STATES (2004), https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/55xx/doc5549/report.pdf; Jeffrey W. Stempel, *Not-So-Peaceful Coexistence: Inherent Tensions in Addressing Tort Reform*, 4 NEV. L.J. 337, 339 (2003) (commenting on the continuation of the "legal, political, social, economic, and rhetorical battle over tort reform"); *Tort Reform*, CONSUMER ATT'YS OF CAL., https://www.caoc.org/?pg=issjustice (last visited Nov. 3, 2022).

2. THOMAS O. MCGARITY, THE PREEMPTION WAR: WHEN FEDERAL BUREAUCRACIES TRUMP LOCAL JURIES 21 (2008) ("The preemption war is a manifestation of the latest and, in many ways, most threatening attempt to change state common law by replacing it with a body of regulatory law that is kinder and gentler to the regulated entities.").

3. *See generally* Ronald Pestritto, *The Birth of the Administrative State: Where It Came from and What It Means for Limited Government*, HERITAGE FOUND. (Nov. 20, 2007), https://www.heritage.org/political-process/report/the-birth-the-administrative-state-where-it-came-and-what-it-means-limited#; Antony Davies & James R. Harrigan, *The Rise of a Massive Federal Bureaucracy*, POST-J. (Jun. 19, 2021), https://www.post-journal.com/opinion/local-commentaries/2021/06/the-rise-of-a-massive-federal-bureaucracy/; Katie Tubb et al., *Supreme Court Takes Up Challenges to near Limitless Power of EPA*, DAILY SIGNAL (Nov. 18, 2021), https://www.dailysignal.com/2021/11/18/supreme-court-takes-up-challenges-to-near-limitless-power-of-epa; Larry P. Arnn, *The Way Out*, 50 IMPRIMIS (Nov. 2021), https://imprimis.hillsdale.edu/the-way-out/.

the turn of the twenty-first century.[4] At the convergence of these seemingly independent issues lies an unassuming point of contention: state tort failure to warn claims based on lack of disclosure to the Food and Drug Administration (FDA).[5]

As a federal administrative agency, the FDA oversees the operation of the national regulatory system for medical devices, promulgating a set of reporting requirements that manufacturers must comply with prior to gaining product approval.[6] Such compliance is not always forthcoming, however, and numerous manufacturers have submitted reports containing fraudulent material to the FDA.[7] Such was the case presented in the seminal Supreme Court case, *Buckman Company v. Plaintiffs' Legal Committee*.[8] Therein, the Court concluded that the plaintiffs' cause of action for "fraud-on-the-FDA" was impliedly preempted under the Medical Device Amendments.[9] Lower courts have subsequently grappled with application of *Buckman's* rationale to state tort failure to warn claims premised, in part, on lack of disclosure to the FDA.[10] This application has come to yield inconsistent results, leading to a split amongst the federal circuit courts as to whether these failure to warn claims based on lack of disclosure are impliedly preempted under *Buckman*.[11]

This Note demonstrates that these state tort claims cannot be impliedly preempted under *Buckman*. Evaluation of the Supreme Court's opinion in *Buckman* reveals that its preemption analysis ought to be narrowly construed

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4. Expert Witness Bio E-007962, *Medical Device Injuries: FDA Data Reveals Increasing Risk*, EXPERT INST. (June 23, 2020), https://www.expertinstitute.com/resources/insights/medical-device-injuries-fda-data-reveals-increasing-risk/; Associated Press, *Medical Devices for Pain, Other Conditions Have Caused More Than 80,000 Deaths Since 2008*, STAT (Nov. 25, 2018), https://www.statnews.com/2018/11/25/medical-devices-pain-other-conditions-more-than-80000-deaths-since-2008/; MedTech Intelligence Staff, *Q3 Medical Device Recalls Increase 36%, Software Issues Remain Top Reason*, MEDTECH INTEL. (Dec. 1, 2021), https://www.medtechintelligence.com/news_article/q3-medical-device-recalls-increase-36-software-issues-remain-top-reason/.

5. *See infra* Section II. This note will focus on intentional failure to disclose, that is, purposefully withholding information, rather than mere negligent or inadvertent lack of disclosure on the part of medical device manufacturers.

6. *See generally* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 344 (2001); Hughes v. Bos. Sci. Corp., 631 F.3d 762, 764 (5th Cir. 2011). These reports take different forms depending on the class of the device and what stage it is at in the approval process.

7. *See, e.g.*, *Buckman Co.*, 531 U.S. at 343; *Hughes*, 631 F.3d at 775.

8. *See Buckman Co.*, 531 U.S. at 343; *Hughes*, 631 F.3d at 775.

9. *Hughes*, 631 F.3d at 775; *Buckman Co.*, 531 U.S. at 344.

10. *See* discussion *infra* Section II.

11. *Hughes*, 631 F.3d at 770.

to apply only to fraud on the FDA claims, which are distinct from state law failure to warn claims based on lack of disclosure.[12] Acceptance of this proposition is consistent with broader policy considerations, namely, the critical role tort liability plays with regards to medical device users and manufacturers, and the preservation of the separation of powers as established by constitutional design.[13]

Part I will provide an overview of the relevant Supreme Court jurisprudence, including a brief explanation of the doctrine of federal preemption, the specific preemption framework under the Federal Food, Drug, and Cosmetic Act (FDCA), and the Supreme Court's opinion in *Buckman*.

Part II will examine the present circuit split and the corresponding rationales of the federal courts from both sides of the preemption divide.

Part III argues that the split ought to be resolved in favor of not preempting state law failure to warn claims premised on lack of disclosure to the FDA, supported by both the legal argument and the broader policy considerations. This section will conclude by addressing and subsequently dismissing competing policy concerns.

I. RELEVANT SUPREME COURT JURISPRUDENCE

A. *The Doctrine of Federal Preemption*

The Supremacy Clause of the United States Constitution lies at the heart of the doctrine of federal preemption, invalidating "state laws that 'interfere with, or are contrary to,' federal law."[14] The preemption analysis rests upon two fundamental "cornerstones:" first, that "the purpose of Congress is the ultimate touchstone in every pre-emption case;"[15] second, "all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,'" require that the analysis begin "with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and

12. *See infra* Section III.A.

13. *See infra* Sections III.B.1 and 2.

14. Hillsborough Cnty. v. Automated Med. Lab'ys, Inc., 471 U.S. 707, 712 (1985) (quoting Gibbons v. Ogden, 22 U.S. 1, 211 (1824)).

15. Wyeth v. Levine, 555 U.S. 555, 565 (2009) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)).

manifest purpose of Congress."[16] The principle necessitating this assumption is protection of "the federal-state balance," ensuring that it will be neither inadvertently upset nor needlessly disrupted by Congress and the Judiciary.[17]

Because the purpose of Congress may be explicitly promulgated through statutory language, or implicitly manifested through a statute's structure and design,[18] the Supreme Court has come to identify two main types of preemption: express and implied.[19] Express preemption arises "when Congress specifies in a federal statute . . . the extent to which it intends that the statute . . . is to oust state power."[20] Implied preemption, which takes on multiple forms,[21] exists where state and federal law are incompatible, nullifying state law "to the extent that it actually conflicts with federal law."[22] Notably, administrative agency action qualifies as federal law for purposes of preemption, [23] effectively permitting unelected administrative officials to specify the degree to which agency regulation will undercut and thereby invalidate state law.

B. *Preemption Framework under the FDCA*

In response to "public outcry" for increased regulation of medical devices following a tragic "series of medical device failures in the early 1970s," Congress enacted the Medical Device Amendments (MDA) with the

16. *Id.* (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)).

17. Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977) (quoting United States v. Bass, 404 U.S. 336, 349 (1971)).

18. *See id.*

19. *See generally* Chamber of Commerce of the United States v. Whiting, 563 U.S. 582, 594, 607 (2011) (discussing express and implied preemption analysis).

20. JAMES M. BECK & ANTHONY VALE, DRUG AND MEDICAL DEVICE PRODUCT LIABILITY DESKBOOK § 5.01, Lexis (database updated May 2022).

21. *See* BECK & VALE, *supra* note 20, at § 5.02. These forms of implied preemption are field preemption, wherein Congress has intended to occupy an entire field by its legislation, and conflict preemption, which is the form presented in *Buckman* and the focus of this Note.

22. Hillsborough Cnty. v. Automated Med. Lab'ys, Inc., 471 U.S. 707, 713 (1985).

23. *See* New York v. FCC, 486 U.S. 57, 64 (1988) ("The statutorily authorized regulations of an agency will pre-empt any state or local law that conflicts with such regulations or frustrates the purposes thereof."); BECK & VALE, *supra* note 20, at § 5.01. *But see* David S. Rubenstein, *The Paradox of Administrative Preemption*, 38 HARV. J.L. & PUB. POL'Y 267, 286 (positing that historical, textual, and structural analysis of the Supremacy Clause indicates that the provision was meant to *exclusively* encompass federal statutes, and that the Constitution does not leave room for agency policies to have preemptive effect).

goal of providing greater consumer protection.[24] The MDA functions as an amendment to the FDCA,[25] giving the FDA the authority to develop and maintain a regulatory system for medical devices.[26] Within the MDA is an express preemption provision, 21 U.S.C. § 360k(a), which provides that the states may not establish any requirement that is "different from, or in addition to," any applicable MDA requirements.[27] The Supreme Court has also read § 337(a) of the Act to impliedly preempt state law, holding out the provision as "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government."[28] Specifically, this MDA provision states that "all . . . proceedings for the enforcement . . . of this [chapter] shall be by and in the name of the United States."[29] Thus, state law claims that rest solely on noncompliance with the MDA are impliedly preempted because authorization to file such suits lies with "the Federal Government rather than private litigants."[30] In other words, implied preemption operates to bar a claim that "seek[s] to privately enforce . . . dut[ies] owed to the FDA," regardless of how the litigant labels such a claim. [31] A state law claim may, however, escape both forms of preemption where the plaintiff sues "for conduct that *violates* a federal requirement (avoiding express preemption)," but does not sue "*only because* the conduct violates that federal requirement (avoiding implied preemption)."[32]

C. *Buckman Company v. Plaintiffs' Legal Committee*

In 2001, the Supreme Court in *Buckman Company v. Plaintiffs' Legal Committee* undertook the challenge of applying the federal preemption doctrine to a newly emerging[33] state law tort claim: fraud on the FDA.[34] In *Buckman*, the plaintiffs suffered injuries from implantation of orthopedic

24. Demetria D. Frank-Jackson, *The Medical Device Federal Preemption Trilogy: Salvaging Due Process for Injured Patients*, 35 S. ILL. U. L.J. 453, 485 (2011).

25. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 344 (2001).

26. Mink v. Smith & Nephew, Inc., 860 F.3d 1319, 1325 (11th Cir. 2017).

27. *Id.*

28. *Buckman Co.*, 531 U.S. at 352.

29. 21 U.S.C. § 337(a).

30. *Buckman Co.*, 531 U.S. at n.4.

31. *Mink*, 860 F.3d at 1327; *see also* Daniel W. Whitney, *Guide to Preemption of State-Law Claims Against Class III PMA Medical Devices*, 65 FOOD DRUG L.J. 113, 122 (2010).

32. Conklin v. Medtronic, Inc., 245 Ariz. 501, 506 (2018).

33. BECK & VALE, *supra* note 20, at § 5.02.

34. *See generally*, *Buckman Co.*, 531 U.S. at 343-53.

bone screws and sought to hold the manufacturer's consulting company liable.[35] Specifically, the plaintiffs claimed that the consulting company made fraudulent representations to the FDA in order to gain market approval for the screws.[36] These representations, in turn, caused the plaintiffs' injuries.[37] In other words, "[h]ad the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured."[38] Despite the noticeable absence of relief for the plaintiffs injured as a result of fraudulent representations to federal agencies,[39] the Court ultimately found that such claims are impliedly preempted.[40] Placing great emphasis on the federal and statutory framework under which the FDA operates, the Court laid out four main considerations in support of its conclusion.[41]

First, it observed that the FDA is vested with ample authority "to punish and deter fraud against the Agency . . . ."[42] Not only does the comprehensive application process include disclosure requirements designed to "detect[], deter[], and punish[] false statements made during . . . [the] approval processes," but the FDA also has a "variety of enforcement options," such as injunctive relief, civil and criminal penalties, or even seizure of the medical device.[43]

Second, the Court highlighted the need for flexibility and discretion in employing these enforcement options within the "statutory and regulatory framework" so as to maintain a "delicate balance of statutory objectives."[44] It reasoned that state law fraud on the FDA claims would hinder the FDA's ability to "police fraud consistently with the Agency's judgment and objectives," an apparent conflict warranting implied preemption.[45]

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35. *Id.* at 343.

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.* at 355 (Stevens, J., concurring) (pointing out that the majority's preemption analysis leaves plaintiffs with no remedy).

40. *Id.* at 348.

41. *Id.* at 347-53.

42. *Id.* at 348 (majority opinion)

43. *Id.* at 349.

44. *Id.* at 348, 349.

45. *Id.* at 350; *see also* Desiano v. Warner-Lambert & Co., 467 F.3d 85, 93 (2d Cir. 2006) ("In other words, *policing fraud on the FDA* through a tort action could interfere with how the FDA might wish to police that kind of fraud itself.").

Third, the Court noted that as a "practical matter," allowing fraud on the FDA claims would increase the burdens on both medical device applicants and the FDA itself,[46] which was contrary to Congressional intent.[47] Permitting each state to determine the adequacy of an applicant's disclosure would expose applicants who had gained FDA approval to "unpredictable civil liability."[48] Further, in an effort to avoid liability, applicants may "submit a deluge of information" to the FDA, leading to greater burdens on the FDA and impedance of the evaluation process.[49]

Fourth, the Court homed in on the fact that state law fraud on the FDA claims "exist solely by virtue of FDCA disclosure requirements," rather than "traditional state tort law which had predated the federal enactments in question[]."[50] Consequently, fraud on the FDA claims would effectively permit private enforcement of FDCA provisions, a function to be exercised exclusively by the United States, as evidenced by the statutory text of 21 U.S.C. § 337(a).[51]

Notably, the *Buckman* Court did not begin the preemption analysis with the presumption against preemption, typically warranted in "situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety. . . .'"[52] Rather, it was careful to draw the distinction between situations where "traditional state tort law principles," are at play and claims involving regulation of fraud against federal agencies, classifying this area as one not "traditionally occupied" by the States and uniquely federal in character.[53]

II. THE CIRCUIT SPLIT

In the years following *Buckman*, a number of federal circuit courts have applied the Supreme Court's reasoning to state law failure to warn tort claims based on lack of disclosure to the FDA, arriving at conflicting legal

46. *Buckman Co.*, 531 U.S. at 350.

47. *See id.*; Frank-Jackson, *supra* note 24, at 454 (Congressional intent being greater consumer protection).

48. *Buckman Co.*, 531 U.S. at 350.

49. *Id.* at 351.

50. *Id.* at 353.

51. *Id.* at 349 n.4.

52. *Id.* at 348 (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)).

53. *Id.* at 347, 352.

conclusions in the process.[54] Among the circuits to have analyzed this specific issue, the Eighth and Eleventh circuits have taken the position that these failure to warn claims are impliedly preempted in light of *Buckman*,[55] whereas the Fifth and Ninth Circuits have determined such claims are not impliedly preempted.[56] The remaining circuits have weighed in on the preemption controversy within this context to varying degrees.[57]

1. Pro-Preemption Rationale

As to the argument favoring implied preemption of failure to warn claims, the reasoning set forth by the Eleventh Circuit in *Mink v. Smith & Nephew, Inc.* is instructive. [58] In *Mink*, the plaintiff underwent a surgical procedure for implementation of a hip replacement system manufactured by

54. *In re* Zantac Ranitidine Prods. Liab. Litig., 546 F. Supp. 3d 1284, 1316 (S.D. Fla. 2021); 4 LOUIS R. FRUMER ET AL., PRODUCTS LIABILITY §24.05, Lexis (database updated Nov. 2022) (indicating the split "developing among the federal circuit courts of appeals as to whether state-law failure-to-warn claims based on the failure to provide disclosures to the FDA are preempted under *Buckman*").

55. Bryant v. Medtronic, Inc. (*In re* Medtronic, Inc.), 623 F.3d 1200, 1205 (8th Cir. 2010); Mink v. Smith & Nephew, Inc., 860 F.3d 1319, 1330 (11th Cir. 2017).

56. Hughes v. Bos. Sci. Corp., 631 F.3d 762, 776 (5th Cir. 2011); Stengel v. Medtronic Inc., 704 F.3d 1224, 1233 (9th Cir. 2013).

57. 2nd Circuit: *See* Pearsall v. Medtronics, Inc., 147 F. Supp. 3d 188, 199 (E.D.N.Y. 2015) (construing failure to warn claim based on the defendant's failure to report adverse events to the FDA required by the PMA process as an attempt to enforce an FDA requirement and thus impliedly preempted under *Buckman*). *But see* Desiano v. Warner-Lambert & Co., 467 F.3d 85, 95 (2d Cir. 2006) (distinguishing fraud on the FDA claims in *Buckman* where "there were no freestanding allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements" from claims premised on traditional state tort duties. Further, the Court found it impossible to read *Buckman* as precluding preexisting common law liability based on other wrongs). 4th Circuit: *See* Williams v. Zimmer US, Inc., No. 5:14-CV-468-F, 2015 U.S. Dist. LEXIS 91238, at *16 (E.D.N.C. July 14, 2015) (finding negligent failure to warn impliedly preempted under *Buckman*, noting that "*Buckman* is not limited to fraud-on-the-FDA claims. Instead, it applies to any claims that depend entirely upon alleged FDCA violations."). 6th Circuit: *See* Waltenburg v. St. Jude Med., Inc., 33 F. Supp. 3d 818, 840 (W.D. Ky. 2014) (holding that failure to warn claims survive implied preemption under *Buckman*, considering the Ninth and Fifth Circuit's decisions in *Stengel* and *Hughes* as the most compelling authorities on the issue). 7th Circuit: *See* Comella v. Smith & Nephew, Inc., No. 13 C 1850, 2013 U.S. Dist. LEXIS 173746, at *7-8 (N.D. Ill. Dec. 11, 2013) (distinguishing state common law duty to warn from fraud claims in *Buckman*, recognizing that plaintiffs' claims were premised on violations of federal regulations, but not impliedly preempted because they were independently capable of existing apart from these regulations as failure of the duty to warn); *see also* Bausch v. Stryker Corp., 630 F.3d 546, 558 (7th Cir. 2010) (finding no preemption of "parallel claims under state law based on a medical device manufacturer's violation of federal law").

58. *Mink*, 860 F.3d at 1330.

the defendant.[59] In the weeks following the operation, chromium and cobalt began leaking from the medical device, increasing the plaintiff's blood toxicity and subsequently causing eye problems and enlargement of an inguinal lymph node that had to be surgically removed.[60] The court found the plaintiff's failure to warn claim based on the defendant's failure to report adverse events to the FDA analogous to the fraud on the FDA claim in *Buckman*.[61] Declining to draw a distinction between claims for making fraudulent representations to the FDA—the fraud claims in *Buckman*—and claims for not disclosing information to the FDA—failure to warn in *Mink*—the court grouped the two together, classifying them both as situations where the manufacturer simply "failed to tell the FDA those things required by federal law."[62] As such, the court determined that the plaintiff's theory premised on the manufacturer's "failure to report" was "not one that state tort law has traditionally occupied," and found the claim impliedly preempted.[63]

Similarly, the Eighth Circuit Court of Appeals in *Bryant v. Medtronic, Inc*. found in favor of implied preemption under the *Buckman* rationale.[64] The defendant in *Bryant* had manufactured an implantable cardiac defibrillator that began causing "unnecessary shocks" to patients implanted with the device.[65] After four years, the defendants "'finally' filed 120 adverse events reports," and shortly thereafter issued a world-wide recall of the device.[66] In response, the class action plaintiffs brought forth a failure to warn claim based on the defendant's failure to provide the FDA with sufficient information or file adverse event reports as required by federal regulations.[67] The court found the claim impliedly preempted, characterizing the plaintiffs' suit as a mere "attempt by private parties to enforce the MDA," one which was expressly "foreclosed by § 337(a) as construed in

59. *Id.* at 1323.

60. *Id.* at 1324.

61. *Id.* at 1330.

62. *Id.*

63. *Id.* ("[H]ere, like *Buckman*, we conclude that federal law preempts these claims insofar as [the manufacturer's] duty is owed to the FDA and [plaintiff's] theory of liability is not one that state tort law has traditionally occupied.").

64. Bryant v. Medtronic, Inc. (*In re* Medtronic, Inc.), 623 F.3d 1200, 1205 (8th Cir. 2010).

65. *Id.* at 1203.

66. *Id.* at 1204.

67. *Id.* at 1205.

Buckman."[68] The court also made reference to the district court's analysis, which draws the following depiction of the plaintiffs' claim: "[p]laintiffs cannot make an end run around [§ 337(a)] by recasting violations of the FDCA as violations of state common law."[69] In short, the Eighth Circuit refused to uphold the plaintiffs' failure to warn claim because proceedings for enforcement of FDCA provisions are exclusively to be made "by and in the name of the United States."[70]

B. *Anti-Preemption Rationale*

In contrast, the Fifth Circuit Court of Appeals in *Hughes v. Boston Scientific Corporation* found the plaintiff's state law failure to warn claim was not preempted "to the extent" that the claim was "predicated on [defendant's] failure to report 'serious injuries' and 'malfunctions' of the device as required by applicable FDA regulations."[71] The plaintiff in *Hughes* sought recovery for second-degree burns from hot liquid that leaked from a medical device the defendant had manufactured.[72] In evaluating the plaintiff's claim under *Buckman*, the court underscored the majority's distinction between fraud on the FDA claims, the existence of which rests solely on FDCA disclosure requirements, and parallel state tort claims that survive preemption by the MDA, where such claims did not arise solely from violation of FDCA requirements.[73] Accordingly, the court viewed the fraud on the FDA claims as an "attempt[] to assert a freestanding federal cause of action based on violation of the FDA's regulations," contrasting it to the plaintiff's assertion of a "Mississippi tort claim based on the underlying state duty to warn about the dangers or risks of [the] product."[74] The court reasoned that the plaintiff's efforts to show the defendant violated FDA regulations was simply a way of proving the defendant's breach of state duty.[75] Moreover, the court compared the plaintiff's failure to warn claim to

68. *Id.* Notably, the court made no reference to *Silkwood v. Kerr-McGee Corp.* and *Kemp v. Medtronic, Inc.*, claims based on traditional state tort law that *Buckman* found exempt from implied preemption. *See infra* Section III.A.

69. *In re* Medtronic Inc., 592 F. Supp. 2d 1147, 1161 (D. Minn. 2009).

70. *Id.* (quoting 21 U.S.C. § 337(a)).

71. Hughes v. Bos. Sci. Corp., 631 F.3d 762, 769 (5th Cir. 2011).

72. *Id.* at 765.

73. *Id.* at 775.

74. *Id.*

75. *Id.*

the tort claims in *Silkwood v. Kerr-McGee Corp.* and *Medtronic, Inc. v. Lohr*, that *Buckman* explicitly recognized as surviving implied preemption.[76] Thus, the reliance on the defendant's violation of FDA regulations was seen not as a barrier to assertion of the failure to warn claim, but rather, a complementary means of establishing the defendant's breach.[77]

The Ninth Circuit Court of Appeals in *Stengel v. Medtronic, Inc.* followed suit, finding the plaintiff's failure to warn claim based on failure to report known risks was not impliedly preempted by the MDA because it was a state law claim that existed "independent of the FDA's pre-market approval process that was at issue in *Buckman*."[78] Going a step beyond *Hughes*, the court even began the analysis with a presumption against preemption,[79] something the *Buckman* Court had found unwarranted.[80] In explaining the necessity of applying this presumption, it relied on the State's strong interest and responsibility in protecting the "lives, limbs, health, [and] comfort," of its citizens by way of its historic police powers.[81]

The concurrence bolstered the majority's argument by offering additional reasons as to why the plaintiff's failure to warn was not impliedly preempted.[82] It first pointed out the same distinctions made in *Hughes* regarding the Supreme Court's decision to uphold *Silkwood v. Kerr-McGee Corp.* and *Medtronic, Inc. v. Lohr*, as cases escaping implied preemption, explaining that *Buckman* "left intact claims 'relying on traditional state tort law which had predated the federal enactments' in question."[83] The concurrence also refused to accept the argument that the plaintiff's failure to warn claim constituted an attempt to enforce an exclusively federal requirement, noting acceptance of this contention would demand "an

76. *Id. Silkwood* involved a state law negligence claim remedies not preempted by the Atomic Energy Act. *See* Silkwood v. Kerr-Mcgee Corp., 464 U.S. 238, 241, 258 (1984). The *Buckman* Court explained that this survived preemption because it was based on state tort law principles of duty of care, and not grounded in a fraud on the agency theory. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 352 (2001). *Medtronic* involved a claim surrounding a manufacturer's duty to use reasonable care and did not center on FDA pre-market approval process, which was wholly federal in character. *See* Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996). The *Buckman* Court found these factors critical to distinguishing such claims from fraud on the FDA.

77. *Hughes*, 631 F.3d at 775.

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

79. *Id.* at 1227-28.

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

81. *Stengel*, 704 F.3d at 1228.

82. *Id.* at 1234-35.

83. *Id.* at 1235 (quoting *Buckman*, 531 U.S. at 353).

unwarranted expansion of *Buckman's* rationale."[84] In its view, state tort claims hold an "important and legitimate role . . . in regulating the adequacy of post-sale warnings for products already on the market,"[85] unlike fraud on the FDA claims that attempted to police "the relationship between a federal agency and the entity it regulates."[86] In essence, the concurrence viewed the source and function of failure to warn claims as factors critical to warranting preservation from implied preemption under *Buckman*.[87]

III. RESOLVING THE CIRCUIT SPLIT

The apparent lack of consensus amongst the circuit courts demands a remedy to escape the present plague of confusion and uncertainty. To halt the construction of this judicial "Tower of Babel,"[88] the question of whether state law failure to warn claims survive implied preemption should be answered in the affirmative. Arrival at this conclusion is achieved by recognition of two underlying principles: 1) analysis of the language and rationale in *Buckman* indicates its reasoning does not apply outside the fraud on the agency context, and 2) a number of broader policy considerations justify survival of failure to warn claims.[89] The latter encompasses two chief considerations, the first being that the value provided by advancement of traditional tort objectives would be lost by preemption of the state tort claim.[90] This includes acknowledgement of the apparent shortcomings of the FDA's regulation of medical devices, which further necessitates preservation of failure to warn litigation.[91] Second, preservation of the constitutional system of separation of powers requires a more restricted application of the preemption doctrine.[92]

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84. *Id.*

85. *Id.*

86. *Id.* (quoting *Buckman*, 531 U.S. at 347).

87. *See id.* at 1234-35.

88. Daniel J. Meador, *A Challenge to Judicial Architecture: Modifying the Regional Design of the U.S. Courts of Appeals*, 56 U. CHI. L. REV. 603, 606 (1989) (arguing inconsistency amongst the circuits creates a "Tower of Babel" effect).

89. *See infra* Sections III.A and B.

90. *See infra* Section III.B.1.

91. *See* discussion *infra* Section III.B.1.

92. *See* discussion *infra* Section III.B.2.

A. *The Legal Argument*

In evaluating the conflicting stances taken by the federal circuit courts, it is crucial to begin with the source of that division, that is, the *Buckman* opinion itself. An accurate understanding of the confines of the Court's analysis, along with the scope of its holding, presents the solution to the preemption dilemma. First, it is imperative to note that *Buckman* itself recognizes that the preemptive scope should be narrow.[93] The Court deliberately distinguished *Silkwood v. Kerr-McGee Corp.*, explaining, "*Silkwood* is different from the present case, however, in [that] . . . *Silkwood's* claim was not based on any sort of fraud-on-the-agency theory, but on traditional state tort law principles of the duty of care. . . ."[94] The Court did not stop there, but thought it important to distinguish *Kemp v. Medtronic, Inc.* as well: "it is clear that the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements."[95] Moreover, it expressly noted that "*Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements . . . ."[96] Read in concert, the *Buckman* Court evidently sought to exempt traditional state law claims—including those that parallel federal safety requirements—from the implied preemption analysis it had applied to the fraud on the agency claim at hand.[97]

With this proposition in mind, an exploration of the nature of failure to warn claims based on lack of disclosure must be undertaken. The failure to warn tort finds classification in one of three possible causes of action: "(1) a warning defect, implicating strict liability; (2) a negligent act on the part of the manufacturer; or (3) an intentional act."[98] Failure to warn claims based on lack of disclosure to the FDA fall within the third category, wherein medical device manufacturers deliberately withhold required information from the FDA.[99] Thus, these failure to warn claims at issue are simply that—state tort failure to warn claims—and the lack of disclosure is merely a

93. *See* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 352 (2001).

94. *Id.*

95. *Id.*

96. *Id.* at 353.

97. *See id.* at 352-53.

98. Daniel R. Cahoy, *Medical Product Information Incentives and the Transparency Paradox+*, 82 IND. L.J. 623, 639 (2007).

99. *See, e.g.*, Bryant v. Medtronic, Inc. (*In re* Medtronic, Inc.), 623 F.3d 1200, 1205 (8th Cir. 2010).

method of demonstrating the manufacturer's breach of duty.[100] The federal safety requirements with which the manufacturer must comply provide the specific warnings it is obligated to disclose, bringing the claim into the realm of those that *Buckman* expressly exempted from its implied preemption analysis.[101] That is, such failure to warn claims are indeed based on "traditional state tort law principles of the duty of care," and do not exist "solely from the violation of FDCA requirements."[102] As such, they are plainly distinct from the fraud on the FDA claims in *Buckman*, and this case ought not be utilized as a means of impliedly preempting such claims.

This finding is reinforced upon consideration of one of the chief arguments presented by the *Buckman* Court in support of preemption, namely, that the FDA has the authority and ability to detect, deter, and punish fraud on the Agency.[103] Such reasoning is inapplicable to preemption of failure to warn claims based on lack of disclosure. Detecting falsely disclosed information, the basis for fraud on the agency claims, and discovering what information the manufacturer has withheld, the basis for failure to warn claims, are separate undertakings entirely, the latter being "fairly difficult to detect."[104] Furthermore, while *Buckman* was concerned that fraud on the FDA claims would "inevitably conflict with the FDA's responsibility to police fraud," and the mechanisms designed to identify false statements made by manufacturers,[105] failure to warn claims do not pose the same concern. Rather, they not only strengthen compliance with FDA reporting requirements, but also provide added deterrence by way of potential tort damages.[106] This thread of the *Buckman* analysis thus fails to present support for preemption of failure to warn claims based on lack of disclosure.

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100. The argument supporting *Buckman's* preemption of fraud on the FDA claims is essentially as follows: if there were no FDA disclosure requirements to begin with, the claim itself would not exist. Fraud on the FDA is a novel claim that would effectively permit private enforcement of FDCA provisions. Failure to warn claims, on the other hand, can and do exist apart from FDA disclosure requirements because there exists an underlying state duty to warn. The FDA disclosure requirements simply provide a way of showing the defendant breached this duty to warn.

101. *See Buckman Co.*, 531 U.S. at 352.

102. *Id.*

103. *Id.* at 349.

104. STEVEN GARBER, ECONOMIC EFFECTS OF PRODUCT LIABILITY AND OTHER LITIGATION INVOLVING THE SAFETY AND EFFECTIVENESS OF PHARMACEUTICALS 17 (2013), https://www.jstor.org/stable/10.7249/j.ctt2jc9fj.10.

105. *Buckman Co.*, 531 U.S. at 349-50.

106. *See infra* Section III.B.1.

The Court's final concern—that permitting fraud on the agency claims may lead to "unpredictable civil liability," increased confusion, and burdens on the FDA and medical device applicants—is not implicated in the context of failure to warn claims premised on lack of disclosure.[107] Because only FDA reporting specifications are utilized to demonstrate that the manufacturer has failed to warn, no novel or conflicting standards among the lower courts will arise by which the manufacturer's conduct may be implicated.[108] As such, there is minimal risk that manufacturers will be confused as to what they are required to report or incentivized to submit more information than required.[109] Accordingly, the FDA will not be on the receiving end of a "deluge of information"[110] that overwhelms and inhibits its efficacy in regulation of medical devices.

Therefore, by the express language of the opinion and inapplicability of the Court's reasoning to claims beyond the fraud on the agency theory, it is apparent that *Buckman* carved out room for survival of traditional state tort claims amidst the implied preemption evaluation.[111] Having ascertained that failure to warn claims based on lack of disclosure fit within this aperture, the conclusion is reached that such claims cannot be deemed impliedly preempted under *Buckman*.

B. *Broader Policy Considerations*

1. Traditional Tort Objectives

Imposition of tort liability serves to advance two goals of paramount societal import: compensation for wronged individuals and encouragement of socially responsible behavior.[112] The benefits derived from the role of tort law relative to the medical device industry, including its effects on both manufacturers and consumers, would be severely diminished by preemption

107. *Buckman Co.*, 531 U.S. at 350.

108. *See infra* Part III.B.3.

109. *See generally, infra* Part III.B.3.

110. *Buckman Co.*, 531 U.S. at 351.

111. *Id.* at 352.

112. VICTOR E. SCHWARTZ ET AL., PROSSER, WADE AND SCHWARTZ'S TORTS, CASES AND MATERIALS 1-2 (14th ed. 2020).

of failure to warn claims.[113] Accordingly, preemption need not function to bar such claims given that tort litigation—and by extension failure to warn claims—is not only compatible with the reasoning presented in *Buckman*,[114] but serves to advance complementary objectives.

As it currently stands, there is no private right of action for a consumer injured by a medical device that has earned FDA approval.[115] Consequently, individuals injured by a manufacturer's lack of disclosure to the FDA are left without a remedy where implied preemption bars the party's failure to warn claim.[116] The very aim of tort law is to "protect people from misfortunes which are unexpected and overwhelming."[117] Furthermore, state law highly values the protection, health, and safety of its citizens.[118] As such, failure to warn tort claims based on lack of disclosure provide this much needed remedy for injured medical device users.[119]

Moreover, given that Congressional intent is the "touchstone" in every preemption case,[120] the fact that tort litigation within this field is not contrary

113. *See generally* Gillian E. Metzger, *Federalism and Federal Agency Reform*, 111 COLUM. L. REV. 1, 32 (2011) (noting Supreme Court decisions to reject preemption of state tort claims for the sake of preserving injured consumers' access to compensation).

114. *See* discussion *supra* Section III.A.

115. *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 487 (1996) ("[T]here is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action."); *see also* Marcia Boumil, *FDA Approval of Drugs and Devices: Preemption of State Laws for "Parallel" Tort Claims*, 18 J. HEALTH CARE L. & POL'Y 1, 6-7 (2015) (explaining that the FDA can issue mandates or withdraw approval of a drug or device, but no private right of action exists for injured consumers).

116. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 355 (2001) (Stevens, J., concurring) (explaining that, in situations where parties are injured by fraudulent representations made to the FDA, preemption of fraud on the FDA claims leave the parties with no remedy). This same result arises if the *Buckman* preemption analysis were extended to failure to warn claims premised upon lack of disclosure to the FDA.

117. Wausau Tile, Inc. v. Cnty. Concrete Corp., 226 Wis. 2d 235, 248 (1999).

118. *See* Stengel v. Medtronic Inc., 704 F.3d 1224, 1233 (9th Cir. 2013) (noting state law's long-time concern with protecting the safety and health of its citizens, including consumers harmed by manufacturers' unreasonable behavior); Pontious v. Medtronic, Inc., No. 11-4069-CM-GLR, 2011 WL 6091749, at *10-11 (D. Kan. Dec. 7, 2011) (articulating that "states have a strong interest in protecting their citizens from . . . personal injuries," as distinct from fraud on the FDA claims where no state interest has traditionally been found).

119. *See* Metzger, *supra* note 113, at 32 (explaining that preservation of injured consumers' access to compensation has been a major factor in the Supreme Courts past decisions in rejecting preemption of state tort claims).

120. Wyeth v. Levine, 555 U.S. 555, 565 (2009) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)).

to the purpose of Congress[121] carries significant weight. As explained by Justice Ginsburg, the MDA failed to "create any federal compensatory remedy for such [injured] consumers[,] further suggest[ing] that Congress did not intend broadly to preempt state common-law suits grounded on allegations independent of FDA requirements."[122] Additionally, in enacting the FDCA, Congress rejected a proposal to "include . . . a private cause of action for injury caused by products regulated by the act . . . *because state common law already provided such a cause of action*."[123] Congressional intent to permit independent state tort actions[124] suggests the implied preemption provision of the MDA ought to be applied in a limited fashion to those claims that have already passed the bar of express preemption and should not be taken as a blanket prohibition on failure to warn claims.

The other valuable contribution of tort litigation is promotion of socially responsible behavior, intertwined with deterrence of wrongful conduct.[125] Permitting state tort actions generally provides added incentive on the part of medical device manufacturers to not only produce safe and effective products, but also helps uncover risks not apparent to the FDA during the approval process.[126] Until the early 2000s, the FDA itself maintained the position that this feedback loop provided by state law failure to warn

121. *See* Efthimios Parasidis, *Patients Over Politics: Addressing Legislative Failure in the Regulation of Medical Products*, 2011 WIS. L. REV. 929, 933 ("Given the limitations of FDA review, tort law has traditionally served as a complementary means of regulating medical products and an additional layer of consumer protection.").

122. Riegel v. Medtronic, Inc., 552 U.S. 312, 337 (2008) (Ginsburg, J., dissenting).

123. Leslie C. Kendrick, *FDA's Regulation of Prescription Drug Labeling: A Role for Implied Preemption*, 62 FOOD & DRUG L.J. 227, 238 (2007) (emphasis added). *See* Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. REV. 559, 616 n.313 (1997) ("The Court has expressed reluctance to intrude upon areas traditionally protected by the states. An example is the Court's recent resistance to imply private rights of action from federal statutes. One of the bases for this resistance has been a fear that such causes of action may unduly interfere with state remedies.") (citing Thompson v. Thompson, 484 U.S. 174, 186 & n.4 (1988)).

124. *See* Kendrick, *supra* note 123, at 238.

125. SCHWARTZ ET AL., *supra* note 112, at 1.

126. *See* David A. Kessler & David C. Vladeck, *The O'Neill Institute for National and Global Health Law: Health Regulation and Governance: A Critical Examination of the FDA's Efforts to Preempt Failure-To-Warn Claims*, 96 GEO. L.J. 461, 463 (2008); *see also* Teresa Curtin & Ellen Relkin, *Preamble Preemption and the Challenged Role of Failure to Warn and Defective Design Pharmaceutical Cases in Revealing Scientific Fraud, Marketing Mischief, and Conflicts of Interest*, 35 HOFSTRA L. REV. 1773, 1779 (2007) ("[L]awsuits brought by private litigants provide a vital and essential role in discovering the hidden dangers of drugs currently on the market.").

litigation was a useful means of enhancing its own performance.[127] Along with uncovering risks of medical devices, affording injured consumers the right to litigate such claims has also exposed "questionable practices by manufacturers," including "fail[ure] to report adverse events to the FDA. . . ."[128] Thus, the ability of failure to warn claims based on lack of disclosure to the FDA to deter inexcusable corporate conduct further compels survival from implied preemption.

Furthermore, the Supreme Court's characterization of the FDA has changed in the years following *Buckman*, shifting from the depiction of a "sophisticated and expert regulator," to the "underresourced agency unable to obtain the information it needs to monitor the multitude of drugs and devices on the market."[129] Numerous commentators have affirmed the proposition that the FDA simply "does not have the resources to perform the Herculean task of monitoring comprehensively the performance of every [device] on the market."[130] The approval process, specifically, has become the subject of extensive criticism.[131] For instance, Elizabeth J. Cabraser,[132] in her thorough examination of the relevant reports, explains how evidence of

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127. Kessler & Vladeck, *supra* note 126; *see, e.g.*, *Riegel*, 552 U.S. at 337-38 (Ginsburg, J., dissenting) (noting that the FDA's chief counsel previously explained: "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 . . . .") (quoting Margaret J. Porter, *The* Lohr *Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 11 (1997)).

128. GARBER, *supra* note 104, at 60.

129. Metzger, *supra* note 113, at 36 (explaining that *Buckman*'s portrayal of the FDA stands in stark contrast to the later 2009 *Wyeth v. Levine* decision).

130. *See, e.g.*, Kessler & Vladeck, *supra* note 126, at 465; Elizabeth J. Cabraser, *Federal Preemption of State Tort Law: A Snapshot of the Ongoing Debate: When Worlds Collide: The Supreme Court Confronts Federal Agencies with Federalism in Wyeth v. Levine*, 84 TUL. L. REV. 1275, 1284 (2010) ("[The FDA] lacks the resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future.") (quoting INST. MED., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 193 (Alina Baciu et al. eds., 2006)); Parasidis, *supra* note 121, at 941 (explaining that the present "lack of resources significantly hinder[s] the ability of the FDA to effectively operate as a regulatory agency").

131. *See, e.g.*, Vincent R. Johnson, *Book Review: Liberating Progress and the Free Market from the Specter of Tort Liability*, 83 NW. U.L. REV. 1026, 1048-49 (1989).

132. Cabraser, *supra* note 130, at 1275 ("Elizabeth J. Cabraser is a partner at Lieff, Cabraser, Heimann & Bernstein, LLP in San Francisco who specializes in consumer fraud, product liability, and tort liability litigation. She filed an amicus brief in support of respondent in *Wyeth v. Levine* on behalf of the National Conference of State Legislatures (NCSL).").

FDA approval process failure is to be found in the astonishing number of medical device recalls.[133] The concerning, yet recurring, theme is that scarce resources severely limit the efficacy of the approval process in maintaining safety across the medical device market.[134] Accordingly, failure to warn claims based on lack of disclosure can both augment the approval process and provide redress for those injured by faulty medical devices.[135]

Therefore, in light of the indispensable role that failure to warn claims—and tort litigation as a whole—play in compensating injured users, incentivizing manufacturers, and supporting the intended regulatory functions of the FDA, the notion that these claims should be impliedly preempted warrants little merit. A manufacturer's deliberate act of withholding information from the FDA, combined with the devastating injuries experienced by innocent medical device users, presents a situation wherein imposition of tort liability upon said manufacturers is far from unjust.

2. Constitutional Design: Separation of Powers

Preservation of constitutional integrity also demands that state law failure to warn claims based on lack of disclosure to the FDA must survive preemption. Broadly put, two patterns of thought underly this notion. First, a broad doctrine of federal preemption that forecloses operation of the state tort claims at issue would facilitate undue expansion of the regulatory power of the FDA in opposition to constitutional safeguards.[136] Second, granting deference to the FDA's interpretation of its own preemptive effects—thereby barring this category of failure to warn claims—would not only permit the administrative agency to play "judge and jury of [medical device] efficacy and safety,"[137] but also allow it to define the extent of its own jurisdictional

133. *Id.* at 1287 ("In 2006, there were 651 recalls involving 1,550 devices.").

134. *See* Parasidis, *supra* note 121, at 933.

135. More specifically, those devices that have fallen through the cracks, so to speak, of FDA regulations.

136. This is not to say that efforts should not be made to increase the efficacy of the FDA. *See* discussion *supra* Section III.B.1. Expansion of the FDA's scope of power and discretion in derogation of the separation of powers, however, is unacceptable given the lack of political accountability and oversight, as discussed above.

137. Cabraser, *supra* note 130, at 1289.

limitations.[138] Thus, the preemption doctrine should be narrowly applied, and a limited deferential position ought to be taken towards FDA preemption determinations, wherein failure to warn claims based on lack of disclosure escape federal preemption.

To establish a constitutional design that preserved the true "expression of the American mind," [139] the Founding Fathers implemented a system of separation of powers, from which emerge three basic tenets: non-delegation, no combination of functions within a single branch, and a clear line of political accountability for administrators.[140] The purpose in establishing a system wherein the executive, legislative, and judicial branches remained separated was for the prevention of tyranny.[141] Specifically, the discretion exercised by the national government would be made safe by attention of the people through clear electoral accountability.[142] The Founders deemed this system "essential to the preservation of liberty,"[143] while at the same time acknowledging that a likely consequence of such a system would be some government inefficiency.[144]

It was precisely this inefficiency, however, from which the progressivist movement in the late nineteenth and early twentieth centuries wished to free agency administrators.[145] Emphasis on the efficiency of administrative agencies and reliance upon their expertise was utilized as justification for

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138. *See, e.g.*, Miss. Power & Light Co. v. Mississippi, 487 U.S. 354, 374, 376-77 (1988) (preempting a Mississippi state agency from determining whether costs were prudently incurred by upholding the FERC's jurisdiction to require a state utility company to purchase power from a nuclear plant).

139. CARLI N. CONKLIN, THE PURSUIT OF HAPPINESS IN THE FOUNDING ERA: AN INTELLECTUAL HISTORY 64 (2019) (quoting Thomas Jefferson, *From Thomas Jefferson to Henry Lee, 8 May 1825*, NAT'L ARCHIVES, https://founders.archives.gov/documents/Jefferson/98-01-02-5212).

140. Pestritto, *supra* note 3.

141. *Id*. at 6.

142. *Id*. (citing THE FEDERALIST NO. 23 (Alexander Hamilton)).

143. THE FEDERALIST NO. 51 (James Madison).

144. *See* Myers v. United States, 272 U.S. 52, 293 (1926) (Brandeis, J., dissenting) ("The doctrine of the separation of powers was adopted by the Convention of 1787, not to promote efficiency but to preclude the exercise of arbitrary power."); INS v. Chadha, 462 U.S. 919, 958-59 (1983) ("[I]t is crystal clear . . . that the Framers ranked other values higher than efficiency. . . . [B]urdens on governmental processes . . . often seem clumsy, inefficient, even unworkable, but . . . [t]here is no support in the Constitution or decisions of this Court for the proposition that the cumbersomeness and delays often encountered in complying with explicit constitutional standards may be avoided. . . . With all the obvious flaws of delay, untidiness, and potential for abuse, we have not yet found a better way to preserve freedom than by making the exercise of power subject to the carefully crafted restrains spelled out in the Constitution."); Rubenstein, *supra* note 23, at 284 (citing THE FEDERALIST NO. 62 (James Madison)).

145. Pestritto, *supra* note 3.

elimination of constitutional checks and balances.[146] In the context of the FDA, this manifests itself as emphasis on the agency's "technocratic and information-processing advantage," and "ability to process detailed scientific research information and complex risk-risk tradeoffs."[147] At first glance, reliance on agency expertise may appear a valid justification for insulating administration from the separation-of-powers system,[148] and thereby the tenet of political control. Indeed, in advocating for broader administrative discretion, Woodrow Wilson declared that "[a]dministration cannot wait upon legislation, but must be given leave . . . to proceed without specific warrant in giving effect to the characteristic life of the State."[149] The issue, however, lies in the reality that, under such an administrative operational framework, "FDA scientists," are effectively given "*carte blanche* to regulate in accord with their own expertise,"[150] completely free from political accountability to the people.

This presents an even greater concern considering that these regulations promulgated by the FDA qualify as federal law for purposes of preemption,[151] and federal preemption of state law, generally speaking, operates to place greater control in the hands of the federal government while simultaneously limiting the authority of state sovereignties. Adoption of a broad preemption doctrine that results in greater foreclosure of state tort claims, including the classic failure to warn, would only furnish the Agency with increased discretion and authority.

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146. *Id.* (first citing Woodrow Wilson, Notes for Lectures at the Johns Hopkins, *in* 7 THE PAPERS OF WOODROW WILSON 122 (Arthur S. Link ed., 1891) ("Give us administrative elasticity and discretion . . . free us from the idea that checks and balances are to be carried down through all stages of organization."); and then citing FRANK J. GOODNOW, SOCIAL REFORM AND THE CONSTITUTION 1,3 (1911) (noting that the Founders' system of government would "retard development" and hinder empowerment of administration)).

147. Peter H. Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 ROGER WILLIAMS U. L. REV. 73, 92-93 (2008) (positing such advantages as justification for federal preemption of state tort law in drug regulation); *see also* Wyeth v. Levine, 555 U.S. 555, 626 (2009) (Alito, J., dissenting) (deferring to the FDA's "expert determinations" in arguing for preemption of state tort law).

148. *See* Peter L. Strauss, *The Place of Agencies in Government: Separation of Powers and the Fourth Branch*, 84 COLUM. L. REV. 573, 596 ("[I]n [administrative] agencies . . . powers are not in fact separated. . . ."); Rubenstein, *supra* note 23, at 325 (noting that agencies in general are "purely national, unelected institutions," lacking in political accountability).

149. Pestritto, *supra* note 3 (quoting Woodrow Wilson, Notes for Lectures at the John Hopkins, *in* 7 THE PAPERS OF WOODROW WILSON 121 (Arthur S. Link ed., 1891)).

150. *Id.* ("[E]xecutive agencies . . . are no longer confined to carrying out specific rules enacted by Congress, but are often left to themselves to determine the rules before seeing to their enforcement.").

151. *See* New York v. FCC, 486 U.S. 57, 63-67 (1988); BECK & VALE, *supra* note 20, at § 5.01.

This concern is not unfounded, as the FDA has gone so far as to put forth declarations concerning the scope of its own preemptive power.[152] Given that the power of an administrative agency is defined by the statute that creates it,[153] this essentially equates to an attempt by the FDA to define the extent of its own jurisdiction. Whether these agency determinations carry any weight, however, is controlled by the amount of deference the courts grant to such promulgations.[154]

Federal courts have previously granted considerable deference to agency preemption determinations, explicitly recognizing that the "FDA is in a unique position to determine the scope of preemption because of its role in the creation of preemptive federal requirements."[155] This degree of deference has shifted over the past two decades, most notably with the Supreme Court's refusal to grant greater deference to the FDA's view of its own preemptive effect in *Wyeth v. Levine*.[156] In *Wyeth*, the defendant argued that the plaintiff's failure to warn claim was preempted because the FDA "must be presumed to have performed a precise balancing of risks and benefits and to have established a specific labeling standard that leaves no room for different state-law judgments."[157] The Court, however, took issue with the fact that the defendant "relie[d] not on any statement by Congress,"

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152. Richard C. Ausness, "*After You, My Dear Alphonse!": Should the Courts Defer to the FDA's New Interpretation of 360k(a) of the Medical Device Amendments?*, 80 TUL. L. REV. 727, 729 ("[I]n 2002, the FDA's Chief Counsel announced that the Agency now believed that most, if not all, common law tort claims should be preempted for medical devices that had received PMA approval. The Agency has espoused this new interpretation of 360k(a) aggressively in amici curiae briefs that it filed in a number of MDA preemption cases."); Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933-34 (Jan. 24, 2006) (later codified at 21 C.F.R. pts. 201, 314, 601) (FDA declaring that the FDCA establishes "both a 'floor' and a 'ceiling,'" so that "FDA approval of labeling . . . preempts conflicting or contrary State law," including failure to warn claims).

153. *See* Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988) ("It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress."); Earl v. Boeing Co., 515 F. Supp. 3d 589, 619 (E.D. Tex. 2021) ("As creatures of statutory origin, agencies are 'restrained by the four corners of its enabling statute and "literally ha[ve] no power to act unless and until Congress confers power upon [them]."'") (quoting Collins v. Mnuchin, 938 F.3d 553, 562 (5th Cir. 2019)).

154. *See generally* Wyeth v. Levine, 555 U.S. 555, 576-78 (2009).

155. Worthy v. Collagen Corp., 967 S.W.2d 360, 375 (Tex. 1998); *see also* Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 228 (2007) (pointing out the existence of "a discernible trend - both in the U.S. Supreme Court and in lower courts - towards deference to agency preemption determinations").

156. *Wyeth*, 555 U.S. at 580-81. In 2006, the FDA included within its new Physician Labeling Rule a preamble stating that the rule preempts conflicting state laws. *Id.* The Supreme Court determined that this preamble did not merit deference and refused to preempt the state law failure to warn claim. *Id.*

157. *Id.* at 575.

in support of its argument, but rather, "on the preamble to a 2006 FDA regulation governing . . . prescription drug labels," wherein the agency "articulated a sweeping position on the FDCA's pre-emptive effect. . . ."[158] No deference, the Court concluded, is merited by "an *agency's mere assertion* that state law is an obstacle to achieving its statutory objectives."[159] The stance taken by the Supreme Court in this case lends weight to espousal of a more narrow construction of the preemption doctrine, as well as a more tailored application of the reasoning regarding preemption of fraud on the agency claims in *Buckman*. Further, this logic set forth in *Wyeth*, combined with the broader trend of limited deference towards agency preemption promulgations,[160] presents a bulwark against administrative agency efforts to interpret the limits of their own power. These factors thus set forth greater support for the argument that failure to warn claims based on lack of disclosure should remain free to exist alongside federal regulations.

In the words of the late Justice Scalia, "there are many desirable dispositions that do not accord with the constitutional structure we live under. And in the long run the improvisation of a constitutional structure on the basis of currently perceived utility will be disastrous."[161] The intent behind including this assertion is not to exhort the total destruction of the modern administrative state. Rather, this principle is presented as a sobering thought and guiding star by which to calculate future decisions implicating the separation of powers. Here, specifically, this manifests itself as adherence to both a narrow preemption doctrine and limited deference toward agency preemption determinations, which aligns with holding state law failure to warn claims exempt from implied preemption.

3. Competing Policy Concerns

Lastly, it is worth dispensing with several common policy considerations raised in favor of impliedly preempting state tort suits, and more specifically,

158. *Id.* at 575, 577.

159. *Id.* at 576 (emphasis added).

160. *See, e.g.*, *In re* Vioxx Prods. Liab. Litig., 501 F. Supp. 2d 776, 788 (E.D. La. 2007) ("Court cannot defer to the FDA in the instant cases because the agency's statements on preemption in the preamble to the 2006 Final Rule lack the 'power to persuade.'"); Reid v. Johnson & Johnson, 780 F.3d 952, 965 (9th Cir. 2015) (declining to give preemptive effect to the 2003 FDA letter concerning its enforcement discretion); BECK & VALE, *supra* note 20, at § 4.01 ("Some FDA positions, not directly formally arrived at, have received only minimal deference from courts, most notably those concerning preemption.").

161. Mistretta v. United States, 488 U.S. 361, 427 (Scalia, J., dissenting).

failure to warn claims. First, it is often posited that permitting failure to warn claims would allow "lay juries,"[162] who are supposedly unable to "process . . . complex risk-risk tradeoffs . . . or second-guess technocratic decisions about [device] design and labeling,"[163] to make "independent determinations about safety."[164] The concern is that the court decisions from fifty different states "could undermine the FDA's regulatory framework by potentially creating conflicting standards that intrude on the FDA's authority."[165] In turn, this would lead to unpredictability and confusion amongst medical device manufacturers who tread the interstate market.[166]

Though a seemingly laudable apprehension, this does not comport with the nature of the American justice system, which "rests upon a faith in . . . juries to rightly find facts" from the evidence presented and explained by attorneys and judges.[167] In fact, "juries are regularly entrusted with extremely technical and difficult material,"[168] and ought not be disregarded simply because they themselves are not so-called "experts."[169] Perceptively formulated by Winston Churchill, "[e]xpert knowledge is limited knowledge: and the unlimited ignorance of the plain man who knows only what hurts is a safer guide[] than any vigorous direction of a specialised character. Why should you assume that all except doctors, engineers, etc. are drones or worse?"[170] Members of the jury need not have professional or specialized knowledge in order to utilize their innate rational capabilities to review the facts presented and render a truly just verdict.

Any fears about the jury's ability to evaluate complex medical issues are further waylaid in light of this particular tort—i.e., failure to warn based on lack of disclosure—wherein the jury is not evaluating whether the

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162. Boumil, *supra* note 115, at 7.

163. Schuck, *supra* note 147, at 93.

164. Boumil, *supra* note 115, at 7.

165. *Id.*

166. *Id.*

167. Christina Marie Martin, *Hugs and Drugs: Research Ethics, Conflict of Interest, and Why the FDA's Attempt to Preempt Pharma Failure-To-Warn Claims is a Dangerous Prescription*, 6 AVE MARIA L. REV. 587, 616 (2008).

168. *Id.*

169. Pestritto, *supra* note 3.

170. Arnn, *supra* note 3 (quoting Winston Churchill's 1901 letter to H.G. Wells).

manufacturer appropriately warned the consumer in the classical sense.[171] Rather, the jury is merely issuing a determination as to whether the manufacturer intentionally failed to submit information that they were required by federal law to report.[172] Thus, an advanced analysis is not required on the part of the jury; it is simply presented with FDA reporting standards, the information possessed by the manufacturer, and evaluates whether the manufacturer withheld said information. Finally, the concern over creation of potentially conflicting standards is unwarranted given that only FDA reporting specifications are under consideration. That is, the jury is not deciding what constitutes an inadequate warning wherein the subsequent ruling will become the new criterion; rather, it is only deciding whether mandatory FDA reporting requirements were deliberately evaded.

Another significant claim frequently raised by advocates for preemption of state tort claims is that civil liability "inhibits innovation, causes desirable products to be withdrawn from the marketplace, and drives companies out of business."[173] Imposition of civil liability under state law for failure to comply with reporting requirements, it is argued, would dissuade drug manufacturers from applying for FDA approval or encourage them to "leave the market altogether."[174] The solution would be to impose broad constraints on legal liability and allow the FDA to utilize its regulatory scheme to police product safety.[175]

On the contrary, consumer utilization of state tort remedies "incentivizes companies to actively monitor their products [and] 'reinforces a norm of attentiveness to safety.'"[176] Thus, rather than hindering innovation, civil tort liability actually spawns positive safety transformations in medical device design and motivates full compliance with FDA reporting requirements on

171. *See, e.g.*, 1 RONALD W. EADES, JURY INSTRUCTIONS ON PRODUCTS LIABILITY § 7.09, Lexis (database updated Aug. 2022) ("If you believe from the evidence that the [manufacturer] [supplier] of the product involved in this action had reason to know of risks in the use of the product, risks which only came to his/her knowledge after the product had left his/her control, and that he/she failed to take steps to warn users of these risks, you may find him/her to be liable for any resultant harm.").

172. This resembles those instructions presented to the jury regarding the government rules defense. *See, e.g.*, *In re* Vioxx Prods. Liab. Litig. v. Merck & Co., 2005 Jury Instr. LEXIS 158 at 19-20 (instructing jury to determine whether the defendant complied with "applicable FDA regulations").

173. A. Mitchell Polinsky & Steven Shavell, *The Uneasy Case for Product Liability*, 123 HARV. L. REV. 1437, 1488-89 (2010).

174. Parasidis, *supra* note 121, at 991.

175. *See id.* at 993.

176. *Id.* at 991 (quoting John C.P. Goldberg & Benjamin C. Zipursky, *The Easy Case for Product Liability Law: A Response to Professors Polinsky and Shavell*, 123 HARV. L. REV. 1919, 1941 (2010)).

the part of manufacturers. Moreover, such arguments for preemption presuppose that the FDA's "regulatory system is capable of generating adequate information related to the safety and effectiveness of medical products, and that regulators have the resources to ensure that this information is disclosed to the public in a timely manner."[177] While administrative agencies, including the FDA, may have once been "cast in nearly heroic terms," thought to consist of "wise experts who could bring intelligent, centralized regulation to remedy the abusive marketplace tactics," this is no longer the case.[178] As established above, the reality is that the FDA is underresourced and presently unsuccessful in its efforts to comprehensively monitor the medical device market.[179]

IV. CONCLUSION

From its inception, American society has experienced significant growth and progress in a variety of fields, characterized by a steady transformation in technological advancement, particularly in the medical device industry. Such development, however, was unfortunately accompanied by increased injuries from said devices, giving birth to efforts to nationally regulate the market for consumer protection purposes.[180] The creation of the MDA, buttressed by civil tort liability, brought about a nationwide standard for medical devices,[181] and allowed for compensation for injured consumers and prompted compliance on the part of the manufacturers.[182]

State tort failure to warn claims based on lack of disclosure play a critical role within this framework, and to impliedly preempt these claims by way of FDA regulations under *Buckman* yields results contrary to the very purpose of the MDA.[183] Furthermore, recognition of implied preemption in favor of sole regulation by the FDA puts undue power in the hands of

177. Parasidis, *supra* note 121, at 990-91 (explaining that this fundamental assumption supports the existence of current preemption law).

178. John Duffy, *Opinion Analysis: The Triumph of the Lanham Act (and of Federal Private Rights of Action)*, SCOTUSBLOG (June 13, 2014, 5:22 PM), https://www.scotusblog.com/2014/06/opinion-analysis-the-triumph-of-the-lanham-act-and-of-federal-private-rights-of-action/.

179. *See supra* Section III.B.1.

180. *See* Frank-Jackson, *supra* note 24, at 485.

181. *See* Mink v. Smith & Nephew, Inc., 860 F.3d 1319, 1325 (11th Cir. 2017) (noting that the MDA gave the FDA the authority to develop and maintain a national regulatory system for medical devices).

182. *See supra* Section III.B.1.

183. *Id.*

unelected administrators, contrary to the Founders' vision for our democratic republic.[184]

It is the "duty [of citizens] to continually reevaluate the framework of government and its ability to pursue its proper end of securing the happiness and safety to the people. . . ."[185] In the present context, technological innovations within the medical device industry cannot be heralded as permission for reconfiguring constitutional design. Rather, state common law tort claims provide the means by which to ensure this "proper end" of government,[186] bringing about what is truly best for this Nation and its people.

184. *See* discussion *supra* Section III.B.2.

185. *See* CONKLIN, *supra* note 139, at 125.

186. *Id.*