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ARTICLES

FDA PREEMPTION: PROS, CONS, & A PATH FORWARD FOR PUBLIC HEALTH IN THE 21ST CENTURY

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INTRODUCTION

In the modern era, the Food and Drug Administration ("FDA") serves a public health role in protecting the public from products that fail to meet safety and efficacy standards and by promoting health through making healthy and aidful drugs, food, and devices available, along with the necessary information to use those products.[1] Given the broad intersection of health regulation from the federal government and the states, preemption greatly affects public health.[2] As federal regulation of health grows more expansive, preemption doctrine becomes more important.[3] There is a delicate balance of state and federal health regulation within the "healthcare federalism" framework.[4]

A recently passed California state law exemplifies how FDA preemption may conflict with state requirements. In October 2023, California passed the California Food Safety Act, which banned four harmful food and drink

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1. Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845, 857 (2017).

2. Lawrence O. Gostin, *The FDA, Preemption, and Public Safety: Antiregulatory Effects and Maddening Inconsistency*, HASTING CTR. REP. 11, 11 (2011), https://scholarship.law.georgetown.edu/facpub/695 [https://perma.cc/CNL5-TX7G]; Elizabeth Y. McCuskey, *Body of Preemption: Health Law Traditions and the Presumption Against Preemption*, 89 TEMPLE L. REV. 95, 96-97 (2016).

3. McCuskey, *supra* note 2, at 97–98; Christine A. Gaddis, *Buckman Extended: Federal Preemption of State Fraud-on-the-FDA Status*, 69 FOOD & DRUG L.J. 113, 114 (2014) (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 475 (1996)).

4. Allison M. Whelan, *The Preemption Prescription: Combatting Health Disparities Caused by State Pharmaceutical Restrictions*, HARV. ADVANCED LEADERSHIP INITIATIVE SOC. IMPACT REV. (Nov. 8, 2022), https://www.sir.advancedleadership.harvard.edu/articles/preemption-prescription-combatting-health-disparities-caused-by-state-pharmaceutical-restrictions [https://perma.cc/4C5M-DH4W].

additives.[5] The restriction will begin in 2027.[6] Currently, all four banned additives are approved by the FDA for usage in food.[7] Many producers are already signaling that they will adapt recipes to California standards, inherently benefitting consumers across the country.[8] But, time will tell if other companies choose to challenge the law on an impossibility preemption basis, using stop-sell rationale.[9] This matter illustrates the constantly evolving and pressing necessity of understanding how FDA preemption affects public health. To address this potential preemption conflict, and other preemption issues moving forward, it may be most prudent for the FDA to argue that there is a presumption in favor of preemption when the agency conducted an informed risk-benefits analysis pre-approval and no new information or considerations are available.[10]

Part I will address the history and development of federal preemption doctrine, including the different types of preemption and the growth of agency preemption.[11] Part II will cover the history of FDA preemption and how it evolved over time, starting with the origination of the FDA and its initial preemption powers.[12] Then, Part II will discuss FDA preemption in the modern era, including the drug versus device distinction and examples of FDA preemption over the last thirty years.[13] Part III discusses the advantages, from a public health lens, of pursuing an "aggressive" versus a "deferential" FDA preemption strategy.[14] Additionally, Part III will analyze three current public health matters to focus the preemption discussion: opioids, obesity, and abortion.[15] Part IV will provide a recommendation for how FDA should pursue preemption strategies in the future to best support public health.[16] Finally, Part V will provide a conclusion.[17]

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5. Joe Hernandez, *California becomes the first state to ban 4 food additives linked to disease*, NPR (Oct. 10, 2023, 1:05 PM), https://www.npr.org/2023/10/10/1204839281/california-ban-food-additives-red-dye-3-propylparaben-candy [https://perma.cc/MEN8-KJMX].

6. *Id.*; Katharina Buchholz, *The Products Affected By The California Food Additives Ban*, FORBES (Nov. 3, 2023, 10:51 AM), https://www.forbes.com/sites/katharinabuchholz/2023/10/13/the-products-affected-by-the-california-food-additives-ban-infographic/?sh=3ccb564e6b7d [https://perma.cc/2LST-XU4V].

7. Hernandez, *supra* note 5.

8. *See infra* Section II.B.2.

9. *See infra* Section II.B.2.

10. *See infra* Part IV.

11. *See infra* Part I.

12. *See infra* Part II.

13. *See infra* Part II.

14. *See infra* Part III.

15. *See infra* Part III.

16. *See infra* Part IV.

17. *See infra* Part V.

I. HISTORY & DEVELOPMENT OF FEDERAL PREEMPTION DOCTRINE

A. How Federal Preemption Doctrine Developed Over Time

Preemption is implicated when, inevitably, state and federal laws overlap.[18] The United States Constitution provides that where a federal law and state law conflict, the federal law prevails.[19] This federal preemptive power arises from the Supremacy Clause.[20] When preemption occurs, the state law is effectively displaced. [21] Courts do traditionally try to find a "presumption against preemption" when evaluating potentially conflicting federal and state legislation, particularly when a federal law is regulating within the traditional state police powers.[22] These police powers include regulation of health and safety.[23] Despite the state hold over police powers, courts do sometimes find that federal laws preempt state health laws, for example, when the purpose of Congress, "'the ultimate touchstone' in determining the scope of preemption," so requires.[24]

B. Overview of the Types of Preemption

A state law is *expressly preempted* by a federal law when Congress "explicitly state[s] its intent to preempt state law" in the legislation.[25] Congress is clearly authorized by the Constitution to preempt state authority through express statement. [26] However, when a federal law directly and expressly preempts in an area considered a traditional state police power, the Supreme

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18. Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 225 (2000).

19. Gibbons v. Ogden, 22 U.S. 1, 129 (1824); Tamsen Valoir & Shubha Ghosh, *FDA Preemption of Drug and Device Labeling: Who Should Decide What Goes on a Drug Label*, 21 HEALTH MATRIX 555, 559 (2012).

20. U.S. CONST. art. VI, § 2; *see also* Chi. & N.W. Transp. Co. v. Kalo Brick & Tile Co., 450 U.S. 311, 317 (1981) (stating Supremacy Clause is root of preemption doctrine).

21. Maryland v. Louisiana, 451 U.S. 725, 746 (1981).

22. Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 516, 518 (1992); Valoir & Ghosh, *supra* note 19, at 560; *see also* Cal. v. FERC, 495 U.S. 490, 497 (1990) ("Just as courts may not find state measures pre-empted in the absence of clear evidence that Congress so intended, so must they give full effect to evidence that Congress considered, and sought to preserve, the States' coordinate regulatory role in our federal scheme."); Altria Grp., Inc. v. Good, 555 U.S. 70, 77 (2008) (explaining how state police powers impact the Court's analysis).

23. Valoir & Ghosh, *supra* note 19, at 560.

24. Thomas A. Costello, *Quitting Cold Turkey: Federal Preemption Doctrine and States Bans on FDA-Approved Drugs*, 26 WM. & MARY BILL RTS. J. 839, 845 (2018) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 347 (2001).

25. Leslie C. Kendrick, *FDA's Regulation of Prescription Drug Labeling: A Role for Implied Preemption*, 62 FOOD & DRUG L.J. 227, 228 (2007) (citing Jones v. Rath Packing Co., 420 U.S. 519, 525 (1977)).

26. Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190, 203 (1983).

Court requires a narrow reading.[27]

While not explicit, *implied preemption* also can block a state law. Implied preemption takes on two forms: field or conflict. Federal courts may find *field preemption* "when an act of Congress touches 'a field in which the federal interest is so dominant that the federal system …'" assumedly precludes any state law enforcement "on the same subject."[28] This may occur when a federal interest in a particular field is so controlling that the federal law "preclude[s] enforcement of state laws on the same subject."[29] For example, in *Rice v. Santa Fe Elevator Corp.*, the Supreme Court found that a congressional statute which set federal requirements over grain storage preempted state laws governing similar grain warehouse practices because "[t]he scheme of federal regulation [was] so pervasive" that it is reasonable to infer "that Congress left no room for the States to supplement it."[30]

Conflict preemption occurs "when there is outright or actual conflict between federal and state law."[31] Conflict preemption either qualifies as impossibility preemption or obstacle preemption.[32] *Impossibility preemption* occurs when complying with both the state and the federal law is physically impossible.[33] This doctrine is illustrated in *Mutual Pharmaceutical Co. v. Bartlett*.[34] In *Mutual Pharmaceutical*, the Supreme Court found that because New Hampshire's design defect claims conflicted with a federal law that precludes generic drug manufacturers from making label changes, it was impossible to comply with both laws, thus, requiring preemption of the state law.[35] *Obstacle preemption* occurs when a state law creates "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[36] For example, in *Crosby v. National Foreign Trade Council*,[37] the Supreme Court preempted a Massachusetts law that prohibited state citizens from buying any goods or services from Myanmar providers.[38] The Court reached decided to apply preemption because the state law conflicted with a

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27. Nelson, *supra* note 18, at 291 (quoting *Cipollone*, 505 U.S. at 518); *see also Medtronic, Inc.*, 518 U.S. at 485 (reasserting narrow preemption reading when in arena of police powers).

28. Valoir & Ghosh, *supra* note 19, at 562 (citing Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

29. Nelson, *supra* note 18, at 227 (quoting *Rice*, 331 U.S. at 230).

30. 331 U.S. at 224–27, 230, 237.

31. La. Publ. Serv. Comm'n v. FCC, 476 U.S. 355, 368 (1986).

32. Nelson, *supra* note 18, at 228.

33. Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–43 (1963).

34. 570 U.S. 472 (2013).

35. *Id.* at 479-80; *see also* Jamie Kendall et al., *FDA Preemption and* Albrecht's *Progeny*, 76 FOOD & DRUG L.J. 579, 579 (2022). New Hampshire argued that the tort liability created a positive duty for manufacturers to create safe products. *Mut. Pharm.*, 570 U.S. at 481.

36. Hines v. Davidowitz, 312 U.S. 52, 67 (1941); *see also* Nw. Cent. Pipeline v. State Corp. Comm'n of Kan., 489 U.S. 493, 509 (1989) ("In the absence of explicit statutory language signaling an intent to pre-empt, we infer such intent . . . because the state law stands as an obstacle to the accomplishment and execution of congressional objectives . . . ").

37. 530 U.S. 363 (2000).

38. *Id.* at 388.

federal act that gave the President power to implement sanctions and created an obstacle for the President in executing his duties.[39]

C. The Development of Agency Preemption

Preemption also extends to agency action.[40] Agencies are able to preempt state law when they act within the scope of the authority delegated to the agency from Congress.[41] Further, the Supreme Court determined that when an agency makes specific determinations based on a comprehensive analysis of risks, express and implied preemption may require overriding state law.[42] For example, in *Williamson v. Mazda Motor of America*, the Supreme Court rested its analysis of whether a federal safety regulation preempted a state tort action primarily on the agency's interpretation of its preemptive force.[43]

Of note, agency preemption is often used as a defense against state tort claims.[44] *Geier*[45] addressed this issue and set the stage for the current agency preemption doctrine.[46] In *Geier*, the plaintiff sued Honda, the defendant, after getting seriously injured in an accident while driving a Honda automobile.[47] The plaintiff argued that the negligent design of the car, specifically, the lack of a driver side airbag, made Honda liable.[48] Honda argued that the National Traffic and Motor Vehicle Safety Act, which Congress enacted specifically to outline vehicle safety measure requirements, preempted the plaintiff's claim.[49] The Supreme Court found that the Department of Transportation safety regulations, arising from this Act, preempted state tort actions against manufacturers who failed to install airbags.[50] The Court reached this decision through conflict preemption analysis—if the state tort remedy prevailed, the Department's comprehensive regulation could not have accomplished its full purpose.[51]

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39. *Id.*

40. *See* La. Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 369 (1986) (explaining that "federal agency acti[on] within the scope of its congressionally delegated authority may pre-empt state regulation.").

41. N.Y. v. Fed. Energy Regul. Comm'n, 535 U.S. 1, 18 (2002).

42. Kendrick, *supra* note 25, at 240-41; *see generally* Geier v. Am. Honda Motor Co., 529 U.S. 861 (2000).

43. Catherine M. Sharkey, *Inside Agency Preemption*, 110 MICH. L. REV. 521, 524 (2012) (citing Williamson v. Mazda Motor of Am., Inc., 562 U.S. 323, 330 (2011)).

44. *See, e.g.*, Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 256 (1984) (finding no preemption of state tort law claims against nuclear facility, even though federal government regulates nuclear safety).

45. 529 U.S. 861 (2000).

46. Sara Rosenbaum, Wyeth v. Levine*: Implications for Public Health Policy and Practice*, 125 PUB. HEALTH REPS. 494, 494–95 (2010).

47. *Geier*, 529 U.S. at 865.

48. *Id.*

49. *Id.*; Costello, *supra* note 24, at 850.

50. *Geier*, 529 U.S. at 864–65, 867.

51. *Id.* at 867, 869–75.

II. HISTORY OF FDA PREEMPTION & EVOLUTION OVER TIME

A. Original FDA Preemption Powers Under the Federal Food, Drug, and Cosmetic Act of 1938

Congress established the FDA through the Pure Food and Drug Act of 1906 and supplemented the agency's responsibilities with the Federal Food, Drug, and Cosmetic Act ("FFDCA") in 1938.[52] The FFDCA created greater regulation of drugs and food on a national scale, with a focus on safety, effectiveness, and proper labeling.[53] Originally, the FFDCA did not include an express preemption provision.[54] Pursuant to the National Uniform Nutrition Labeling[55] and Safe Medical Device Amendments,[56] FDA is now granted express preemption authority over inconsistent state law requirements.[57] Beyond this express preemptive power, like other federal agencies, the FDA also has extensive implied preemptive authority through the Supremacy Clause and the Commerce Clause.[58] When discussing FDA preemption, it is important to understand that FDA's jurisdiction covers medical products, *not* the practice of medicine (which is a distinct area of regulation reserved for the states).[59]

B. FDA Preemption in the Modern Era

Traditionally, FDA is willing to work with states to avoid preemption where possible.[60] In the past, the FDA only pursued preemption in cases not involving

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52. *Milestones in U.S. Food and Drug Law*, FDA (Jan. 30, 2023), https://www.fda.gov/about-fda/fda-history/milestones-us-food-and-drug-law.

53. Valoir & Ghosh, *supra* note 19, at 563–64; McCuskey, *supra* note 2, at 133 ("The FDA oversees the testing, approval, labeling, and marketing of drugs, devices, radiation-emitting products, vaccines, blood, biologics, animal and veterinary food, drugs, cosmetics, tobacco products, and supplements."); *see also* U.S. CONST. art. I, § 8, cl. 3 (giving Congress the authority to regulate interstate sales through the Commerce Clause, which may include sale of food and drugs).

54. 21 U.S.C. § 301.

55. *Id.* § 343-1.

56. *Id.* § 360(k).

57. FOOD & DRUG L. INST., A PRACTICAL GUIDE TO FDA'S FOOD AND DRUG LAW AND REGULATION 83–84 (Stephen M. Kanovsky & Wayne L. Pines eds., 7th ed. 2020) [hereinafter A PRACTICAL GUIDE].

58. *Id.*; *see also* U.S. CONST. art. I, § 8, cl. 3; U.S. CONST. art. VI, § 2.

59. Zettler, *supra* note 1, at 849 ("The 'crucial distinction between product and practice regulation' is the cornerstone of federalism in pharmaceutical regulation. . . . [C]ourts, lawmakers, and [FDA] itself have long opined that state jurisdiction is reserved for medical *practice*—the activities of physicians and other health care professionals—and federal jurisdiction for medical *products*, including drugs.") (quotations omitted).

60. A PRACTICAL GUIDE, *supra* note 57, at 83–84; Kendrick, *supra* note 25, at 231 (stating that the FDA historically "embraced state tort law as complementary to its regulatory mission").

state tort liability.[61] For example, in *Jones v. Rath Packing Co.*,[62] the FDA submitted an amicus brief arguing for preemption over a state regulation that conflicted with a federal regulation.[63] In *Eli Lilly & Co., Inc. v. Marshall*,[64] the court found that the FDA's confidentiality practice preempted a state court order requiring disclosure of information protected under federal regulation.[65] The FDA also relied on a floor-ceiling model of drug regulation—where FDA regulations set the floor (the minimum) requirements and state tort suits set the ceiling (the maximum) for liability.[66] This aligns with the judiciary's tradition of avoiding preemption of state tort laws where there is a lack of a comparable federal remedy.[67]

However, over time, the FDA seems more eager to pursue preemption.[68] For example, during the Bush Administration, the FDA started to assert that certain state laws which add or differ from the federal medical product requirements are preempted.[69] Additionally, in 2006, FDA stated in a preamble to a final rule on prescription drug package inserts that the FDA prescription drug labeling preempts state failure-to-warn claims in some scenarios.[70] While the FDA stated this is a long held position, this regulation marked the first time that the agency so blatantly expressed a pro-preemption position.[71] The preemption position asserted by FDA in this context is an implied preemption view.[72] To support this position, the FDA relies on its history of comprehensive drug labeling authority.[73] The FDA further expressed concern that state law

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61. Kendrick, *supra* note 25, at 231; *but see* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001) (evaluating state "fraud on the FDA" causes of action through a preemption lens).

62. 430 U.S. 519, 522 (1977).

63. *Id.* at 522–24 (finding federal laws that regulate net weight labeling for meat packages preempt similar state regulations); *see also* Grocery Mfr. of Am., Inc. v. Gerace, 755 F.2d 993 (2d. Cir. 1985) (holding that federal regulation about descriptive cheese labeling, arising from FFDCA, preempts state cheese imitation law because provisions are in direct conflict).

64. 850 S.W.2d 155, 158 (Tex. 1993).

65. *See generally id.*

66. Michael R. Abrams, *Renovations Needed: The FDA's Floor/Ceiling Framework, Preemption, and the Opioid Epidemic*, 117 MICH. L. REV. 143, 152–53 (2018).

67. Amanda Frost, *Judicial Review of FDA Preemption Determinations*, 54 FOOD & DRUG L. J. 367, 375 (1999) (citing Symens v. SmithKline Beecham Corp., 152 F.3d 1050, 1055 (8th Cir. 1998)).

68. Kendrick, *supra* note 25, at 232.

69. A PRACTICAL GUIDE, *supra* note 57, at 97.

70. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) ("FDA is the expert [f]ederal public health agency charged by Congress with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading.") Whether or not the preamble declaration should receive judicial deference, is up for debate. *See* Kendrick, *supra* note 25, at 233, 236.

71. Kendrick, *supra* note 25, at 233, 227.

72. *Id.* at 227.

73. *Id.*

labeling requirements may lead to misbranding of a drug.[74] More recently, FDA asserted statutory preemption in the Skin Protectant Rule[75] and the Bottled Water Rule.[76] The agency asserted that the Skin Protectant Rule gives express preemption through 21 U.S.C. § 379r(a) and that the Bottled Water Rule deserves preemptive effect through the misbranded food regulation of 21 U.S.C. § 403A.[77] However, it is important to note that FDA assertions are not law and are subject to potential challenges.

In the modern era, FDA preemption frequently arises in state failure-to-warn cases. Failure-to-warn claims are actions brought against drug manufacturers alleging that the manufacturer failed to provide adequate caution as to the risks of a certain drug that harmed a user (the plaintiff).[78] A manufacturer may use a preemption defense to defend its labeling choices when the state requirements conflict with the federal requirements for drug labeling.[79]

1. Drug Versus Device Distinction in Preemption

Current Supreme Court precedent reaches different preemption holdings with relation to drugs versus devices. Broadly, federal labeling requirements do not preempt state tort claims against drugs, but federal labeling requirements do preempt state tort claims against medical devices.[80] This is a complicated area of FDA preemption, because the Supreme Court is quite nuanced in its analysis. In under four years, the Court ruled that state tort litigation against FDA medical devices and stare failure-to-warn claims against generic drugs are preempted, while holding that state failure-to-warn claims against *brand name drugs* are *not* preempted.[81] The main difference between device regulation and the rest of the regulations under the FFDCA is the express preemption provision[82]—which is part of why the Supreme Court has issued varying preemption rulings for drugs versus devices. The primary example of this dichotomy is *Wyeth*[83] versus *Riegel*,[84] as outlined further below.[85]

In the drug space, misbranding is a hot topic in FDA preemption. One of the FDA's core functions is eliminating misbranding vis-à-vis making sure that

74. 71 Fed. Reg. at 3935 (providing examples of types of state failure-to-warn claims that are preempted by FDA labeling requirements).

75. 21 C.F.R. §§ 310, 347 (2009).

76. *Id.* §§ 129, 165.

77. Sharkey, *supra* note 43, at 548.

78. Kendall et al., *supra* note 35, at 579.

79. *Id.* (citing Merck Sharp & Dohme Corp. v. Albrecht, 587 U.S. 299, 302–04 (2019)).

80. Valoir & Ghosh, *supra* note 19, at 555; *see generally* Wyeth v. Levine, 555 U.S. 555 (2009); Riegel v. Medtronic, Inc., 552 U.S. 312 (2008).

81. Gostin, *supra* note 2, at 11; *see also Wyeth*, 555 U.S. 555; *Riegel*, 552 U.S. 312; PLIVA, Inc. v. Mensing, 564 U.S. 604, 618 (2011).

82. 21 U.S.C. § 360k(a) (2012); Valoir & Ghosh, *supra* note 19, at 569.

83. Wyeth, 555 U.S. 555.

84. Riegel, 552 U.S. 312.

85. *See infra* notes 91–101, 109–13 and accompanying text.

drugs are labeled properly and that drug advertising is truthful.[86] When a new drug is approved, the drug manufacturer and the FDA work together to develop the drug label, with the FDA giving final approval; if the manufacturer wants to change the label in the future, the agency must approve any substantive change.[87] The *Wyeth* case largely centered around the FDA's "changes being effected" ("CBE") regulation. CBE allows a drug manufacturer to simultaneously bolster the safety language on a drug label before receiving FDA approval and to notify the FDA of the intended change.[88] A manufacturer may only utilize the CBE process if they knew or should have known about the newly acquired information, if the newly acquired information shows an association between an effect and the drug, and the casual association warrants adding a warning.[89] In practice, this CBE regulation is rarely used and typically only applies in emergency situations as a narrow exception for newly discovered risks.[90]

In *Wyeth v. Levine*, the plaintiff received Phenergan, a drug for migraine treatment from Wyeth (the defendant drug manufacturer).[91] If injected into an artery, Phenergan may cause gangrene, a dangerous medical condition that can result in long-term injury.[92] When the plaintiff received her Phenergan injection, the drug went into her artery, leading to gangrene and amputation.[93] The plaintiff consequently brought a negligence and strict liability lawsuit against Wyeth, claiming that Wyeth inadequately labeled the drug, leading to the injuries she received through the IV push method of injection.[94] Wyeth argued that the plaintiff's claims are preempted because it was impossible to modify Phenergan's label without violating federal law and because the "state tort action creates an unacceptable 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'"[95]

The Supreme Court held that a state failure-to-warn claim is not preempted unless the state law claims are clearly in tension with the FFDCA.[96] *Wyeth* represents a consumer-centric, anti-preemption approach.[97] Despite the FDA's preamble asserting its preemptive effect over state failure-to-warn claims, the Supreme Court disagreed and "refused to defer to . . . FDA's position on

86. 21 U.S.C. § 331(a), (b) (2006); Valoir & Ghosh, *supra* note 19, at 565.

87. Kendall et al., *supra* note 35, at 580.

88. 21 C.F.R. § 314.70(c)(1)-(5) (2016).

89. Kendall et al., *supra* note 35, at 582 (citing Dolin v. GlaxoSmithKline L.L.C., 951 F.3d 882, 885 (7th Cir. 2020)); *see also* 21 C.F.R. § 314.70(b)(2)(v)(A) (2016).

90. Valoir & Ghosh, *supra* note 19, at 566–67 (citing Background and Proposed Amendments, 73 Fed. Reg. 2850 (Jan. 16, 2008) (to be codified at 21 C.F.R. pts. 314, 601, 814)).

91. Wyeth v. Levine, 555 U.S. 555, 559 (2009).

92. *Id.*

93. *Id.*

94. *Id.* at 559–60.

95. *Id.* at 563–64 (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

96. Kendall et al., *supra* note 35, at 580; *see also Wyeth*, 555 U.S. at 581.

97. Rosenbaum, *supra* note 46, at 496.

preemption."[98] The Court determined that the FDA regulations create a floor, rather than a ceiling, for the required warnings.[99] Impossibility preemption did not apply because, through the CBE process, Wyeth could have changed the label unilaterally without the FDA's prior approval.[100] Thus, the Supreme Court ultimately found that the state law presented no obstacle to the purpose of the FFDCA, and thus, there is no preemption of state failure-to-warn suits against pharmaceuticals.[101]

Medical device cases also shed light on preemption. For example, in *Cipollone*, the Supreme Court determined that federal regulations preempted product liability claims against medical devices.[102] After the plaintiff's mother, a smoker, died due to lung cancer, he sued a cigarette manufacturer for failure-to-warn of the cigarette's harm.[103] The defendant manufacturer argued that the Public Health Cigarette Smoking Act, a federal statute, preempted the claims because the Act requires a specific warning to appear on all cigarette packets.[104] The Supreme Court determined that the statute did indeed preempt the state law claims because Congress considered preemption and explicitly included preemptive effect in the statute.[105]

The Medical Device Amendments of 1976 ("MDA"), which amended the FFDCA, added explicit language clearly granting FDA preemptive powers over device regulations (akin to the Public Health Cigarette Smoking Act in some respects).[106] The MDA came in the wake of the Dalkon Shield crisis and at a time when some states had already enacted medical device regulations.[107]

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98. Sharkey, *supra* note 43, at 546 (citing *Wyeth*, 555 U.S. at 577); *see also Wyeth*, 555 U.S. at 576–79 (determining that FDA's preamble asserting preemption is not persuasive because "it reverses the FDA's own longstanding position without providing reasoned explanation").

99. *Wyeth*, 555 U.S. at 575–76.

100. Rosenbaum, *supra* note 46, at 496.

101. *Wyeth*, 555 U.S. at 578, 581; *see also* Valoir & Ghosh, *supra* note 19, at 559–80 (describing Court's findings that Congress consistently decided not to preempt state law through FFDCA and that public policy requires holding drug companies accountable for their warning labels).

102. Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MISSOURI L. REV. 895, 904 (1994) (citing Cipollone v. Liggett Grp., Inc., 505 U.S. 504 (1992)); *see also* Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

103. *Cipollone*, 505 U.S. at 508–09 .

104. *Id.* at 508, 510. The Act states: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." 15 U.S.C. § 1334(b) (1988).

105. *Cipollone*, 505 U.S. at 517; *see also id.* at 524 ("Thus, insofar as claims under either failure-to-warn theory require a showing that respondents' post-1969 advertising or promotions should have included additional, or more clearly stated, warnings, those claims are pre-empted.").

106. 21 U.S.C. § 360k(a) (2012); Leonard H. Glantz & George J. Annas, *The FDA, Preemption, and the Supreme Court*, 358 NEW ENG. J. MED. 1883, 1885 (2008).

107. Valoir & Ghosh, *supra* note 19, at 568–69.

Accordingly, Congress included an express preemption clause in the MDA.[108]

In *Riegel v. Medtronic, Inc.*, the Supreme Court held that the express preemption clause of the MDA preempts state law claims against the safety and efficacy of devices approved through the FDA's pre-market approval process.[109] The injured plaintiff argued that he had a case against Medtronic, the device manufacturer, because the design, labeling, and manufacturing of the device violated New York law.[110] The Supreme Court determined that since the state common law claims imposed different requirements than the FDA's pre-market approval process to evaluate the safety and effectiveness of a device, preemption applied.[111] Justice Ginsburg issued a sole dissent in *Riegel*.[112] She argued that because the Medical Device Amendments were intended to improve public health by protecting from dangerous devices, Congress could not have intended to take away the right of an injured patient to sue the manufacturer of a faulty device.[113] The dissent tracked closely with *Wyeth* and the floor-ceiling model.[114]

2. Prime Examples of FDA Preemption – 1990s to Present

As explained above,[115] state tort claims against medical devices are generally preempted by express preemption.[116] However, in *Medtronic, Inc. v. Lohr*,[117] the Supreme Court evaluated whether the medical device requirements from the FDA preempt state law tort claims for injuries that arise from a medical device approved through the 510(k) process. The Supreme Court held that the requirements did not preempt the claims.[118] Even though 510(k) relates to medical devices, the Court determined that the manufacturing and labeling requirements fell outside the preemption provision.[119] Coming out of

108. 21 U.S.C. § 360k(a) ("[N]o 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.").

109. *See generally* Riegel v. Medtronic, 552 U.S. 312 (2008).

110. Gaddis, *supra* note 3, at 118–19.

111. *Riegel*, 552 U.S. at 330.

112. *Id.* at 333–45 (Ginsburg, J., dissenting).

113. Glantz & Annas, *supra* note 106, at 1885 (discussing J. Ginsburg dissent in *Riegel*).

114. *See supra* note 66–67 and accompanying text, discussing floor-ceiling model.

115. *See generally supra* Section II.B.1.

116. *See, e.g.*, King v. Collagen Corp., 983 F.2d 1130 (1st Cir. 1993) (determining MDA preempted state law failure-to-warn claims against cosmetic medical device); Martin v. Medtronic, Inc., 254 F.3d 573 (5th Cir. 2001) (holding that because manufacturer complied with the FDA's "rigorous premarket approval procedure," plaintiff's "common law products liability tort claims are preempted by . . . the Medical Devices Amendments"); Rattay v. Medtronic, Inc., 482 F. Supp. 2d 746 (N.D. W.V. 2007) (finding state strict liability, negligence, and failure-to-warn claims against medical device (catheter) manufacturer preempted).

117. 518 U.S. 470 (1996).

118. *Id.*

119. *Id.* at 501.

Medtronic, the Court seemed to draw a line between general requirements—which are not preemptive—and specific determinations – which do carry a preemptive force.[120]

Next, in *Buckman Co. v. Plaintiffs' Legal Comm.*,[121] the Supreme Court found that state fraud-on-the-FDA claims are preempted by federal regulations through implied conflict preemption.[122] Fraud-on-the-FDA state statutes eliminate drug manufacturer protection from product liability when a plaintiff proves the manufacturer misrepresented data or information to the FDA during the market approval process.[123] *Buckman* involved Class III medical devices approved by the FDA through the § 510(k) process.[124] The plaintiffs in this suit alleged that the manufacturer "made fraudulent representations to . . . the [FDA]" when obtaining market approval and that the fraudulent representations gave rise to their injuries.[125] In determining that the claims were preempted, the Supreme Court noted that the presumption against preemption is inapplicable in this case, despite dealing with health and safety, because the case "involve[s] the relationship between a federal agency and the entity it regulates."[126] Further, the Court emphasized that these fraud-on-the-FDA claims serve to potentially upset the careful balancing act done by the FDA in approving such devices.[127] The state claims also could increase the burden on device applicants by potentially creating liability for manufacturers under the FFDCA and each individual state scheme.[128]

Later, in *PLIVA, Inc. v. Mensing*,[129] the Supreme Court found that despite *Wyeth*, state failure-to-warn claims are preempted when brought against *generic* drug manufacturers, as the state cause of action directly conflicts with federal generic drug regulation.[130] In arguing before the Court, the generic drug manufacturer asserted that it was impossible to comply with the state and federal labeling requirements, as each jurisdiction required different labels.[131] The Court reasoned that since under the Hatch-Waxman Act[132] generic manufacturers cannot unilaterally change a drug label through CBE, it would be impossible for a generic drug manufacturer to "simultaneously satisfy their state

120. Kendrick, *supra* note 25, at 240.

121. 531 U.S. 341 (2001).

122. *Id.* at 348; *see also* Gaddis, *supra* note 3, at 124 (outlining preemption decision, claim type, and outcome for major drug and device preemption cases in chart).

123. Gaddis, *supra* note 3, at 113.

124. *Id.* at 122.

125. *Buckman*, 531 U.S. at 343.

126. Gaddis, *supra* note 3, at 123 (quoting *Buckman*, 531 U.S. at 347).

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

128. *Id.* at 350.

129. 564 U.S. 604 (2011).

130. *Id.* at 618, 626.

131. Peter Grossi & Daphne O'Connor, *FDA Preemption of Conflicting State Drug Regulation and the Looming Battle Over Abortion Medications*, 10 J.L. & BIOSCIENCES 1, 13 (2023).

132. 21 U.S.C. § 355(j).

law duty to pro[vide] additional warning and their federal law duty to provide the same labeling as the brand name drug."[133]

The Court solidified this decision in *Mutual Pharmaceutical Co. v. Bartlett*.[134] The plaintiff sued a generic drug manufacturer for injuries, allegedly due to unsafe drug design, since the drug label did not warn the plaintiff of the risk of a rare and serious condition she developed.[135] The Court found impossibility preemption barred the design defect claims.[136] Further, the Court disregarded the plaintiff's argument that impossibility could be avoided if the manufacturer just stopped selling its drug in the state as a means of compliance.[137]

PLIVA receives criticism for making such a strong distinction between brand and generic drugs. This is because an individual's ability to bring a failure-to-warn claim against a manufacturer will turn on whether the pharmacist dispensed a brand or generic name drug on the day in question.[138] With generic drugs continually carving out a greater market share, preemption will likely overcome more consumer, state law claims over time.[139] As long as the Hatch-Waxman Act stands as is, the Court's distinction between brand and generic name drugs is supported by federal law to some degree.[140]

FDA preemption also occurs when a state tries to enact less restrictive regulations than the FDA. For example, in *Ouellette v. Mills*,[141] a federal district court judge found that federal law preempted a Maine law that allowed patients to import unapproved drugs from specific countries.[142] Congress gave the FDA authority to inspect imported drugs and detain any drug that seems adulterated or in violation of United States drug regulations.[143] Notably, Maine (unsuccessfully) constructed its law to fall within the practice of medicine sphere, rather than product regulation.[144]

An example of preemption in the food space arose from state food additive regulations. The FFDCA requires the FDA premarket approval of additive usage, but the FDA's final rule does not require notification about GRAS

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133. Sharkey, *supra* note 43, at 551 (citing *PLIVA*, 564 U.S. at 606).

134. 570 U.S. 472 (2013).

135. *Id.* at 478–79.

136. *Id.* at 475, 485–87.

137. *Id.* at 487–88.

138. Gostin, *supra* note 2, at 12; *see also* Abrams, *supra* note 66, at 162 ("Consumers often play no role in the decision between a generic or brand-name drug that ends up impeding their path to recovery.").

139. Gostin, *supra* note 2, at 12 ("Currently, the prescriptions for more than 90 percent of drugs for which a generic version exists are filled with generics.").

140. 21 U.S.C. § 355(j).

141. 91 F. Supp. 3d 1 (D. Me. 2015).

142. Zettler, *supra* note 1, at 848 (citing *Oullette*, 91 F. Supp. at 12).

143. 21 U.S.C. § 381(a).

144. Jones v. Rath Packing Co., 430 U.S. 519, 540–43 (1977); Cosmetic, Toiletry & Fragrance Ass'n, Inc. v. Minnesota, 440 F. Supp. 1216, 1222 (D. Minn. 1977), *aff'd*, 575 F.2d 1256 (8th Cir. 1978).

substance use.[145] However, California enacted the Sherman Act, which only allowed limited quantities of added unsafe substances in food.[146] In *Sciortino v. Pepsico, Inc.*,[147] a federal court determined that because the relevant federal laws, the Delaney Clause and the Color Additives Amendment, did not contain express preemption provisions, the state law could stand.[148] This case involved a California law that required an additional warning label, based on safety concerns, on products with certain color additives.[149] Manufacturers raised preemption claims because the FDA previously determined that the additive met a minimum safety threshold, though its FFDCA authority.[150] The court reached this conclusion through relying on the presumption against preemption, bolstered by the fact that the state action fell within the realm of traditional police power regulations.[151]

Most recently, in 2019, the Supreme Court addressed preemption of failure-to-warn claims in *Merck Sharp & Dohme Corp. v. Albrecht*.[152] *Albrecht* built upon *Wyeth* to set up a clearer standard for impossibility preemption analysis when analyzing pharmaceutical failure-to-warn claims: (1) determine if sufficient evidence exists to trigger the manufacturer's ability to add the desired warning label to the product (unilaterally through CBE) and (2) if so, present "clear evidence … that FDA would not have approved such changes."[153] The plaintiff can only proceed if the manufacturer actually possessed the information needed to cure the labeling deficiency through CBE at the time the plaintiff took the drug.[154] While the Court did not reach a decision on the merits about whether preemption occurred, the majority did emphasize that preemption is a question of law that a court, rather than a jury, should determine.[155]

III. IS IT BETTER TO PURSUE AN AGGRESSIVE OR DEFERENTIAL FDA PREEMPTION STRATEGY FOR PUBLIC HEALTH?

The FDA contributes to public health by aiding in treatment and prevention of diseases and unsafe products through food and drug regulations.[156] There is

145. 21 C.F.R. § 170.30 (2024); Laurie J. Beyranevand & Diana Winters, *Retooling American Foodralism*, 44 AM. J.L. & MED. 489, 500–01 (2018).

146. Beyranevand & Winters, *supra* note 145, at 501 (citing CAL. HEALTH & SAFETY CODE §§ 110545–110655 (West 1970)).

147. 108 F. Supp. 3d 780 (N.D. Cal. 2015).

148. *Id.* at 805–06 (citing 21 U.S.C. §§ 379e(b)(5)(B), 379e(a)).

149. Beyranevand & Winters, *supra* note 145, at 501.

150. *Id.*

151. *Id.* at 501–02.

152. 587 U.S. 299 (2019).

153. Kendall et al., *supra* note 35, at 580, 582 (citing *Albrecht*, 587 U.S. at 307-11).

154. *Id.* at 589–90.

155. *Albrecht*, 587 U.S. at 307–09.

156. McCuskey, *supra* note 2, at 129, 131.

an ongoing debate as to what degree of preemption best serves public health.[157] Looking at the advantages of various preemption strategies, as well as the effect of preemption on current public health issues, can shed light on how to approach FDA preemption moving forward. But, it is important to note that to adopt either strategy, certain federal statutory changes may be necessary.

A. Advantages of Pursuing an Aggressive FDA Preemption Strategy

A main benefit of preemption is that it creates national uniformity across drug, device, and food regulations.[158] With greater federal preemptive force, states will likely be less inclined to try to enact contradictory or supplementary state laws. Uniformity may also increase innovation and access,[159] as without the fear of litigation, drug manufacturers may be more willing to try out new products and less likely to increase prices. Additionally, uniformity can decrease health disparities that arise when certain states enact regulations that impact access.[160]

Preemption may serve as a greater protector than litigation, because litigation rarely is corrective or additive to safety.[161] Even if an aggressive preemption strategy is utilized, this does not mean that private litigants are precluded from bringing any and all lawsuits.[162] While preemption will inherently decrease litigation, drug companies are now required to publish clinical trials and adverse event summaries, providing greater clarity and information to the FDA through other channels than at FFDCA's enactment.[163] Additionally, the FDA can rely on other "helpers" that watch and regulate the drug industry, such as watchdog groups and citizen petitions.[164]

Aggressive preemption can lead to better actions by manufacturers (at least theoretically). Drug companies may use amounting litigation costs as a reason to increase drug prices, which in turn, limits access to drugs and harms public health.[165] Again, aggressive preemption can also serve a stronger role in protecting innovation. Without greater fear of state tort litigation, manufacturers may more willingly develop and promote new drugs to treat chronic and rare

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157. A PRACTICAL GUIDE, *supra* note 57, at 97.

158. *See* Glantz & Annas, *supra* note 106, at 1884 ("The theory behind preemption is that some activities . . . require nationally uniform federal regulation."); Zettler, *supra* note 1, at 852 (illustrating how federal regulation of drugs arose as a response to "disparate state laws").

159. McCuskey, *supra* note 2, at 111.

160. Whelan, *supra* note 4.

161. Valoir & Ghosh, *supra* note 19, at 589.

162. Glantz & Annas, *supra* note 106, at 1884 (citing Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984)).

163. Valoir & Ghosh, *supra* note 19, at 557.

164. *Id.* at 592.

165. Rosenbaum, *supra* note 46, at 496; *see also* Wyeth v. Levine, 555 U.S. 555, 582 (2009) (Breyer, J., concurring) ("I also note that some have argued that state tort law can sometimes raise prices to the point where those who are sick are unable to obtain the drugs they need.").

diseases.[166]

Further, preemption gives FDA the first bite at making product safety and availability determinations. One could also argue that drug and medical device regulation, as a highly scientific and technical field, is not within the general police powers of health and safety, and thus, should defer to federal laws as a default. Strong preemption creates standard, minimum protections, based on safety, efficacy, and science.[167]

This strategy also avoids the issue of over-warning. Plaintiffs will usually present a compelling argument in the courtroom, as they are able to offer a tragic story. However, this may result in manufacturers inserting an overly expansive package insert that can bury the important information.[168] Over-warning can also lead to under prescription of a beneficial medical product, which can diminish public welfare, if patients are not getting the drugs they need.[169] The FDA already is conducting important balancing analysis to make sure that the benefits and risks are presented and measured for each product on the market, and it is best to respect this evaluation.[170] Pursuing a more aggressive preemption strategy across the board may bring drug and device preemption policies into greater alignment.[171] Additionally, just because Congress did not include a broad express preemption provision in all parts of the FFDCA does not mean it completely ruled out implied preemption.[172]

B. Advantages of Pursuing a Deferential FDA Preemption Strategy

The FDA frequently relies on the states to help with enforcement, through regulating facilities and performing manufacturer inspections.[173] By avoiding preemption, the FDA can better foster these state relationships. As the Supreme Court even acknowledged, given the limited resources of the agency, state laws compliment the FDA's drug regulation.[174] The FDA also tends to lack sufficient resources, so state tort claims can fill in these gaps and provide additional,

166. Rosenbaum, *supra* note 46, at 497.

167. McCuskey, *supra* note 2, at 111–12; Costello, *supra* note 24, at 852.

168. Valoir & Ghosh, *supra* note 19, at 557.

169. *Id.*

170. *See id.* at 557–58. It is important to note that the FDA notoriously takes a long time to make decisions; a truth that should be factored into this preemption strategy analysis. So, while the balancing analysis is important, it can take an exorbitant amount of time for the agency to complete.

171. *See id.* at 580–82 ("[T]here is no reason to treat the two products differently. Both types of medical product are highly regulated—indeed, the regulatory regimes for drugs and Class III PMA devices are largely analogous. Each requires a detailed approval application including copious safety and efficacy data, as well as detailed manufacturing and packaging specifications, including the proposed text and layout of the package insert, which provides instructions for use of the drug or device.").

172. Kendrick, *supra* note 25, at 239.

173. A PRACTICAL GUIDE, *supra* note 57, at 83–84.

174. Wyeth v. Levine, 555 U.S. 555, 577–79 (2009).

needed monitoring of manufacturers.[175] A deferential preemption strategy also allows states to fill in the gaps where greater food regulation could improve public health and safety.[176] With regards to food specifically, over-preemption and a uniform food safety approach may diminish local and sustainable food systems, because national standards can create heavy burdens and high costs for smaller producers.[177]

Further, FDA regulations inherently encompass traditional police powers of health and safety and there is not enough in the legislative history to suggest that Congress intended to completely override these powers through the FFDCA.[178] Deferential preemption allows the floor-ceiling model of FDA drug regulation to play out in a more balanced way (as intended).[179] This strategy also permits state governments to react to public health issues in a more timely and efficient manner, too.[180] States should retain the ability to address the public health systems in their own communities, even when involving FDA-regulated products.[181] Moreover, this approach aligns with the legislative history of the FFDCA. When Congress passed the FFDCA originally, it decided not to include a proposal for a private cause of action for those injured by products regulated under the Act, because such a remedy was already available through state common law.[182]

Additionally, taking away state tort suits eliminates the ability of injured patients to receive compensation.[183] When the FDA is given broad authority to preempt state laws of recovery in the realm of defective drugs and devices, patients lose their main option for recourse.[184] The anti-preemption strategy leaves these potential remedies open to patients. Without the protection of preemption, drug manufacturers may more actively seek to change and update drug labels to reflect comprehensive warnings about a drug, given that they want to avoid litigation.[185] Consumers are arguably more protected under a

175. Costello, *supra* note 24, at 851 (citing *Wyeth*, 555 U.S. at 578–79).

176. Beyranevand & Winters, *supra* note 145, at 498.

177. *Id.* at 497.

178. La. Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 369 (1986); Jared C. Huber, *Preemption Exemption: FDA-Approved Abortion Drugs After Dobbs*, 98 NOTRE DAME L. REV. 2217, 2228 (2023).

179. Abrams, *supra* note 66, at 153.

180. Jason P. Block, *The Calorie-Labeling Saga – Federal Preemption and Delayed Implementation of Public Health Law*, 379 NEW ENG. J. MED. 103, 104 (2018) (discussing delay in calorie count requirements due to preemptive federal law); Whelan, *supra* note 5.

181. *See* Zettler, *supra* note 1, at 896–97.

182. Kendrick, *supra* note 25, at 238 (citing H.R. 6110, 73d Cong. § 25 (1933); S. 1944, 73d Cong. § 24 (1933).

183. Wyeth v. Levine, 555 U.S. 555, 579 (2009) ("State tort suits . . . also serve a distinct compensatory function . . . ").

184. Glantz & Annas, *supra* note 106, at 1885; Lawrence O. Gostin, *Regulating the Safety of Pharmaceuticals: The FDA, Preemption, and the Public's Health*, 301 J. AM. MED. ASS'N 2036, 2037 (2009).

185. *See* Gostin, *supra* note 2, at 11–12.

deferential preemption strategy.[186] Moreover, without litigation against drug and device manufacturers, the FDA loses a useful tool in gathering additional safety data and ensuring that these companies are actually complying with laws and regulations.[187]

Finally, aggressive preemption severely limits the states' ability to influence the federal government to adopt certain policies[188] through serving as a living laboratory[189] or making policy that more accurately reflects public desire, given that state officials are elected (and those in agencies are not). This is especially important because federal agencies historically do not give much weight to state opinion.[190] Thus, this weighs in favor of a deferential preemption strategy.

C. Looking at Three Current, Public Health Issues: Opioids, Obesity, and Abortion

1. Opioids and Preemption

The United States is currently experiencing a public health crisis due to opioid misuse, addiction, and overuse.[191] About two million Americans are addicted to or misuse prescription opioids, with many of these users moving on to "stronger illicit drugs" after developing substance use disorder.[192] The United States prescribes opioids at higher rates than other countries and, consequently, experiences high fatalities attributed to prescription opioid use.[193] Moreover, nearly half of all overdoses in 2015 are attributed to FDA-approved drugs.[194] Beyond death, opioids also may cause the development of a substance use disorder, impaired cognitive function, and other debilitating symptoms.[195] Given the FDA's involvement in drug regulation, the agency can play a role in

186. Rosenbaum, *supra* note 46, at 496–97. However, it is debatable whether consumer protection and ability to seek compensation for injuries is an element of "public health."

187. Valoir & Ghosh, *supra* note 19, at 557, 582; *see also Wyeth*, 555 U.S. at 579 ("State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly."); Gostin, *supra* note 2, at 12 ("In 2009, the FDA issued a 'black box warning' about the very drug at issue in *PLIVA*—metoclopramide, also known as Reglan. Litigation revealed that manufacturers knew the risks but did not promptly inform the FDA.").

188. Beyranevand & Winters, *supra* note 145, at 496–98; Zettler, *supra* note 1, at 850-51.

189. McCuskey, *supra* note 2, at 112.

190. Zettler, *supra* note 1, at 896.

191. Patricia J. Zettler et al., *Implementing a Public Health Perspective in FDA Drug Regulation*, 73 FOOD & DRUG L.J. 221, 221 (2018); *see also* Abrams, *supra* note 66, at 149.

192. Zettler et al., *supra* note 191, at 229.

193. *Id.* at 222 (stating that in 2016, opioid overdoses caused 42,000 fatalities, with forty percent of those deaths attributed to prescription opioids).

194. Zettler, *supra* note 1, at 846 ("The Centers for Disease Control and Prevention (CDC) reported that in 2015, drug overdoses resulted in over 52,000 deaths, and overdoses have eclipsed motor vehicle crashes as the leading cause of injury-related death in the United States.").

195. Zettler et al., *supra* note 191, at 225.

decreasing the potential harms of opioids.[196]

When states try to take matters into their own hands, FDA preemption often proves fatal. The prime example of this is *Zogenix, Inc. v. Patrick*.[197] FDA approved Zohydro, "a new high-dose opioid that lacked abuse-deterrent properties" in October 2013.[198] The drug entered the market in March 2014.[199] Shortly after, the Governor of Massachusetts prohibited the sale and prescription of Zohydro within the state until the manufacturer reformulated the drug to include abuse-deterrent properties, as an attempt to address the opioid epidemic.[200]

As a result, the manufacturer of Zohydro filed suit in federal court, asking for a preliminary injunction on the ban.[201] Massachusetts argued that the ban fell within the practice of medicine regulation because it governed the manner of prescribing and dispensing of Zohydro.[202] But, in April 2014, a federal district court judge enjoined the prohibition on Zohydro, finding the FFDCA preempted Massachusetts's ban.[203] The judge determined that if the ban stood, "it would undermine the FDA's ability to make drugs available to promote and protect the public health." [204] Following the injunction, the Massachusetts Board of Registration in Medicine enacted a regulation that limited who may handle Zohydro, put ample restrictions on pharmaceutical dispersion of the drug, and required a letter of medical necessity pre-prescription.[205] Initially, the District Court granted the manufacturer's preliminary injunction, through implied obstacle preemption,[206] but the court revoked the injunction upon a showing of "adequate and constitutional guidance to [the] physicians" from Massachusetts

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196. *Id.* at 221. It is important to note that the FDA's powers are somewhat limited or effected by other agencies (i.e., Drug Enforcement Administration ("DEA")) that also play a role in drug regulation.

197. No. 14-11689-RWZ, 2014 WL 1454696 (D. Mass. Apr. 15, 2014).

198. Zettler, *supra* note 1, at 846.

199. *Id.* at 847; *see also* Costello, *supra* note 24, at 852 (stating that in 2014, Massachusetts had the thirteenth-highest drug overdose rate of any state).

200. Zettler, *supra* note 1, at 847, 872.

201. Costello, *supra* note 24, at 843.

202. Zettler, *supra* note 1, at 872.

203. Zogenix, Inc. v. Patrick, No. 14-11689-RWZ, 2014 WL 1454696, at *2 (D. Mass. Apr. 15, 2014).

204. *Id.*

205. Zogenix, Inc. v. Patrick, No. 14-11689-RWZ, 2014 WL 3339610, at *2 (D. Mass. Aug. 28, 2014); *see also* Zogenix, Inc. v. Baker, No. 14-11689-RWZ, 2015 WL 1206354, at *2 (D. Mass. Mar. 17, 2015) ("On April 22, 2014, the Commonwealth's Board of Registration in Medicine ('BORIM') promulgated an emergency regulation requiring an individually licensed prescriber to take certain steps before prescribing Zohydro, including supplying a letter of medical necessity confirming that other pain management treatments had failed. Similarly, on May 6, 2014, the Commonwealth's Board of Registration in Pharmacy ('BORIP') promulgated two Zohydro-related regulations. The first, which I will call the 'pharmacist-only' regulation, stated that '[a] certified pharmacy technician, pharmacy technician, pharmacy technician trainee, or pharmacy intern may not handle [Zohydro].' The second contained a host of prerequisites a pharmacist must satisfy before dispensing Zohydro.").

206. Costello, *supra* note 24, at 843–44; *see also Zogenix*, 2014 WL 3339610, at *2, *4–*5.

and a change in law that other pain management is deemed "inadequate," not failed.[207] The ending result created a much less arduous and stringent regulation of Zohydro than the state originally desired.

Ultimately, while Massachusetts tried to improve public health by eliminating sales of a drug that lacks abuse-deterrent qualities, at a time when opioid addiction is rampant, preemption operated to prevent the state remedy. The problem here is that the cost to public health is not borne by the manufacturers.[208] As generic drug sales continue to take a large share of the market, drug manufacturers will continue receive greater insulation from the state tort liability "ceiling" and less frequently bear the cost, leaving society and individuals to deal with the consequences.[209] While other solutions, such as a public nuisance suit, could provide this balance, preemption doctrine may create a more wide-reaching solution.[210]

2. Obesity and Preemption

Obesity is another chronic public health issue in America.[211] More than 60% of adults in the United States are obese or overweight.[212] As part of the Affordable Care Act ("ACA"), Congress enacted a law requiring restaurant chains with at least twenty locations to start putting calorie counts on menus.[213] The focus on restaurant calorie counts arose due to the increasing reliance on eating out in America[214] and on the heels of numerous state law requirements on labeling and calorie disclosure.[215] In 2018, eight years after its passage, the calorie labeling requirement finally took force.[216]

Calorie labeling may potentially create a more calorie-conscious society and aid in obesity prevention.[217] Given the fractured requirements across states, and the frustration that it caused for national chains, food-industry groups generally supported a federal requirement if it would preempt state and local requirements.[218] Resultingly, the FDA asked states to halt implementation—but then, due to an arduous notice and comment process, the public health measure

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207. *Zogenix*, 2014 WL 3339610, at *1; *Zogenix*, 2015 WL 1206354, at *2.

208. Abrams, *supra* note 66, at 148–49, 159 (discussing the 2015 cost of opioid epidemic, from The White House Council of Economic Advisers, as more than $500 billion).

209. *Id.* at 157.

210. *Id.* at 165.

211. Lainie Rutkow et al., *Preemption and the Obesity Epidemic: State and Local Menu Labeling Laws and the Nutrition Labeling and Education Act*, 36 J. L., MED., & ETHICS 772, 772 (2008).

212. *Id.*

213. 21 U.S.C. § 343(q)(5); Block, *supra* note 180, at 103.

214. Rutkow et al., *supra* note 211, at 772.

215. *Id.* at 775–76; Block, *supra* note 181, at 103.

216. Block, *supra* note 180, at 103.

217. *Id.* at 105.

218. *Id.* at 103.

took years to reach fruition.[219] As a result, while preemption had the potential to create wide-sweeping and efficient public health benefits, it actually served to slow progress.

3. Abortion and Preemption

Perhaps most recently, rampant debate has emerged about whether state laws that restrict or ban access to abortion medication, in conflict with the FDA's approval, are preempted.[220] It is further unclear whether FDA action may preempt a ban based on health and safety versus a ban based on morality.[221] Access to mifepristone, "the abortion pill," is considered crucial to ensure that reproductive health care is available across the country.[222] Additionally, state-level restrictions on abortion medication access "disproportionately impact vulnerable and historically marginalized communities, particularly people of color, low-income populations, persons with disabilities, and the LGBTQ+ communities."[223]

Following the *Dobbs*[224] decision, the Biden Administration released a statement that the FDA regulation of mifepristone preempts any state regulations that are contrary to the agency's determinations of safety and efficacy.[225] The FDA asserts that the REMS and ETASU on mifepristone show that the agency conducted extensive balancing of risks and benefits when approving and modifying the prescription of the drug, too.[226]

Obstacle preemption may serve as a means to invalidate state restrictions on mifepristone that "encroach on the FDA's purview over drug safety and effectiveness—including the agency's responsibility to promote public health by making safe and effective drugs available."[227] Using Mississippi as an example, the additional requirements on prescription and dispersion, such as a 24-hour waiting period and ingestion of the pill in an abortion facility, may create an obstacle to the FDA's purpose of regulation.[228] Specifically, some advocates argue that the state restrictions block patient access, which mollifies

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219. *Id.* at 103–04.

220. *E.g.*, Huber, *supra* note 178, at 2218–19.

221. *Id.* at 2250–51; Rachel L. Sher, *FDA Preemption: Implications of Dobbs Decision for Uniform Access to FDA-Approved Drugs in the U.S.*, MANATT (Aug. 8, 2022), https://www.manatt.com/insights/newsletters/health-highlights/fda-preemption-implications-of-dobbs-decision-for [https://perma.cc/V23L-RV6D].

222. Patricia J. Zettler & Ameet Sarpatwari, *State Restrictions on Mifepristone Access – The Case for Federal Preemption*, 386 N. ENG. J. MED. 705, 706 (2022).

223. Whelan, *supra* note 5.

224. Dobbs v. Jackson Women's Health Org., 597 U.S. 215 (2022).

225. U.S. DEP'T OF JUST., NO. 22-663, ATT'Y GEN. MERRICK B. GARLAND STATEMENT ON SUP. CT. RULING IN DOBBS V. JACKSON WOMEN'S HEALTH ORG. (June, 24, 2022).

226. *See* Patricia J. Zettler et al., *Mifepristone, preemption, and public health federalism*, 9 J.L. & BIOSCIENCES 1, 14 (2023) [hereinafter *Mifepristone*].

227. Zettler & Sarpatwari, *supra* note 222, at 706.

228. *Mifepristone*, *supra* note 226, at 13–14.

the FFDCA's purpose and objectives.[229]

Impossibility preemption could also create FDA preemption over state mifepristone restrictions. The FDA could argue that where states ban or so greatly restrict a drug such that a manufacturer cannot sell its product in that state, that creates an impossibility.[230] In such a scenario, a court may find that since a manufacturer cannot comply with the state and federal regulations without stopping selling in that state, the law is preempted.[231]

Just as the Zohydro cases prove insightful to the opioid crisis and preemption, they also apply to mifepristone.[232] Similarly to *Zogenix, Inc. v. Patrick*, a court may find that the FDA's public health mission supports finding preemption of state restrictions.[233] Also, as with opioids, the FDA put a REMS on mifepristone after making a calculated risk-benefits analysis.[234] This supports a potential obstacle preemption claim against state restrictions on the sale of mifepristone.[235]

Others argue that state bans of mifepristone are not preempted by current federal regulations, because Congress never intended for the FDA "to have exclusive, comprehensive domain over drug regulations."[236] It follows that even if a drug is found safe and effective by the FDA, that does not mean the drug must be sold in all fifty states.[237] This is bolstered by the fact that the FFDCA lacks any express preemption provision with regards to drugs.[238] However, public health may likely be better supported by uniformly ensuring drugs are available across the entire country.

IV. PUBLIC HEALTH FOCUSED RECOMMENDATION FOR FUTURE FDA PREEMPTION STRATEGY

While precedent and the FFDCA should guide the determination of whether FDA regulations preempt state laws and restrictions, the FDA's own position and the Court's reasoning have changed frequently over the last one hundred years. Thus, considering the advantages of each position, as outlined above,[239] and the particularities of current public health issues in evaluating what position

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229. *Id.* at 14; Grossi & O'Connor, *supra* note 131, at 36–37 (citing in-person provider visits as an example of a state law that may face obstacle preemption).

230. *Mifepristone*, *supra* note 227, at 17–18; *see, e.g.*, Mut. Pharm. Co. v. Bartlett, 570 U.S. 472 (2013) (finding that stopping selling is not an option to complying with both state and federal law, because it leads to impossibility preemption of state law).

231. Grossi & O'Connor, *supra* note 131, at 35; *Mifepristone*, *supra* note 226, at 18.

232. *See supra* Part III.C.1.

233. *Mifepristone*, *supra* note 226, at 19–21.

234. *Id.* at 14.

235. Huber, *supra* note 178, at 2249 n.226.

236. *Id.* at 2220.

237. *Id.* at 2234–35; *see also id.* at 2245 ("The [FFDCA] permits the nationwide sale of an approved drug. The [FFDCA] does not require the nationwide sale of an approved drug.").

238. *Id.* at 2220.

239. *See supra* Part III.

the FDA should advocate for when moving forward is helpful. But, it is important to also recognize that the Supreme Court seems to continually move towards a more aggressive preemption doctrine.[240] With that in mind, the question becomes: how can we tailor this presumption *in favor* of preemption to best serve public health?

One suggestion is to pursue preemption when the FDA has completed "a careful balancing of competing interests" using science and technical considerations when no new information or considerations are available.[241] This risk-benefit preemption approach is already adopted and used by some courts.[242] When Congress requires the FDA "to do a complex balancing of numerous considerations," such as determining if an REMS is needed, and if so, what to include in the REMS, "a court might reasonably conclude that state requirements additional to those in an FDA-required REMS pose an obstacle to the FDA's responsibility to satisfy these Congressional objectives."[243] Further, the REMS provisions of the FFDCA clearly task the FDA with considering health care system burdens and patient access to drugs.[244]

This analysis might require a state, in supporting its additional restrictions or requirements on a drug, for example, to show that based on new information or on the unique local and substantial needs of the jurisdiction, the FDA's value judgment is incorrect and that the risk-benefit analysis is better balanced with the state law.[245] This balancing approach to preemption is fruitful. While there are many disadvantages to aggressive FDA preemption,[246] it is a measured strategy. The approach also aligns with the Court's current presumption in favor of preemption.[247]

Pursuing preemption when the FDA completed a balancing of risks and benefits may explain and possibly lead to better outcomes, too. For example, in *Buckman*,[248] this can support the Court's finding of preemption better than the old reliance on the floor-ceiling model.[249] Further, this approach may lead to a more consistent and health-focused outcome in the *Wyeth-PLIVA* brand name-generic distinction. Rather than basing the determination of preemption on if the

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240. *See supra* Part II, III.

241. *See* Valoir & Ghosh, *supra* note 19, at 557.

242. Zettler, *supra* note 1, at 868; *see also* Jones v. Rath Packing Co., 430 U.S. 519, 540–43 (1977) (preempting "a California law establishing a standard for weight variance in bagged flour that differed from the federal law"); *see also* Cosmetic, Toiletry & Fragrance Ass'n., Inc. v. Minnesota, 440 F. Supp. 1216, 1222 (D. Minn. 1977), *aff'd*, 575 F.2d 1256 (8th Cir. 1978) (preempting a Minnesota law that required additional chlorofluorocarbon warnings on cosmetics).

243. Zettler, *supra* note 1, at 875; *Mifepristone*, *supra* note 226, at 14–15; *see, e.g.*, *Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 1454696 (D. Mass. Apr. 15, 2014) (first *Zogenix* case enjoining Massachusetts' efforts to ban Zohydro).

244. 21 U.S.C. § 355-1(f)(2).

245. Costello, *supra* note 24, at 857.

246. *See supra* Section III.B.

247. *See supra* text accompanying note 246.

248. *See supra* text accompanying notes 120–27.

249. *See supra* note 66–67 and accompanying text, discussing floor-ceiling model.

drug manufacturer made a unilateral decision, the risk-benefit analysis will prevail. If the plaintiff can prove that there is new information, not part of the risk-benefit calculus, that posits a new risk, then that creates potential for non-preemption. Additionally, this proposed preemption strategy better aligns with the Court's reasoning in *Medtronic*, by giving preemptive force to the FDA's specific determinations.[250] This is more public health conscious than the current blanket rule approach of preemption versus non-preemption for different product categories.

Additionally, this helps alleviate the pains of how long it takes the FDA to make decisions and issue rules.[251] When the agency is taking time to reach a determination, state laws govern in the interim. This approach can also allow for local regulations to stand if there is unique information specific to that jurisdiction that did not receive weight in the analysis from the FDA, which can alleviate some of the downsides of a national system.[252] For all this to occur though, the Hatch-Waxman Act likely needs to be amended. Such a legislative change would increase the validity of this strategy, as it would provide the FDA with a reasoned explanation for the change, like the Court noted in *Wyeth*.[253]

This preemption strategy is also clearly beneficial in the obesity and abortion contexts. If this approach had been applied in the calorie labeling scenario,[254] since the FDA had yet to promulgate rules and regulations, the state laws could have stood until the agency completed a risk-benefit analysis and issued the final rule. In future conflicts, such as the California Safety Food Safety Act additives ban,[255] this is an opportunity to see if the FDA's risk-benefits calculus involved a full picture of the cancerous properties of the additives when it approved the usage many years ago. Potentially, this could serve as a catalyst for the FDA to reevaluate its previous decisions, too. The risk-benefit analysis for finding preemption will also provide uniform access to mifepristone. Given that the FDA placed a REMS and ETASU on the drug,[256] it is likely this risk-benefit analysis would yield in favor of preemption.[257]

Applying this framework to opioids is more complex. Just like with mifepristone, the FDA can use the REMS process to demonstrate a thoughtful risk-benefit analysis in allowing these painkillers to stay on the market. While this likely means a case like *Zogenix* would still come down in favor of preemption, [258] the framework may encourage the agency to put greater restrictions on drugs that pose higher risks, in order to show the thoughtful process behind the drug approval decision.

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250. *See supra* notes 117–19 and accompanying text.
251. *See supra* note 160.
252. Rutkow et al., *supra* note 211, at 773.
253. *See supra* note 98; Wyeth v. Levine, 555 U.S. 555, 576 (2009).
254. *See supra* Section III.C.2.
255. *See supra* text accompanying notes 5–8.
256. *See supra* text accompanying note 233.
257. Sher, *supra* note 219.
258. *See supra* Section III.C.1.

V. CONCLUSION

Over time, the United States preemption doctrine continues to develop and evolve.[259] Through express and implied preemption, the doctrine became more deferential to agencies.[260] For the FDA specifically, the nuances of the FFDCA and the brand name versus generic distinction makes preemption analysis sometimes frustrating and not always public health minded.[261] There are many pros and cons to pursuing an aggressive or deferential FDA preemption strategy, and the consequences of the FDA's approach may bear directly on current public health crises.[262] Consequently, it is recommended that moving forward, the FDA should argue for, and the courts should adopt, an FDA preemption strategy that favors preemption when the FDA conducts a risk-benefits analysis with all available information in approving a product.[263] This approach likely requires amendment of current legislation or regulations, such as the Hatch-Waxman Act, to fully realize the strategy in all facets of FDA preemption in the future.[264] Such legislative amendment can further bolster and allow for the proposed public health preemption strategy to succeed.

259. *See supra* Part I.
260. *See supra* Section I.C.
261. *See supra* Part II.
262. *See supra* Part III.
263. *See supra* Part IV.
264. *See supra* Part IV.