

## NOTES

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### PREEMPTION EXEMPTION: FDA-APPROVED ABORTION DRUGS AFTER *DOBBS*

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#### INTRODUCTION

*Dobbs v. Jackson Women's Health Organization* held that no constitutional right to abortion exists,<sup>1</sup> overruling *Roe v. Wade* and *Planned Parenthood of Southeastern Pennsylvania v. Casey*.<sup>2</sup> After *Dobbs*, states are free to regulate abortion as they see fit.<sup>3</sup> Under *Roe* and *Casey*'s old regime, a state could not regulate abortion in a way that presented an "undue burden on a woman's ability" to decide to abort.<sup>4</sup> The Court handed down many cases which attempted to bring clarity to the murky standard.<sup>5</sup> But the conglomeration of interpretation is now wiped away.

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1 See *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2242 (2022).

2 *Dobbs*, 142 S. Ct. at 2242 ("We hold that *Roe* and *Casey* must be overruled."). In overruling these two landmark cases, the Court also abrogated a number of others. See, e.g., *Doe v. Bolton*, 410 U.S. 179 (1973); *Colautti v. Franklin*, 439 U.S. 379 (1979); *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016); *June Med. Servs. L.L.C. v. Russo*, 140 S. Ct. 2103 (2020).

3 *Dobbs*, 142 S. Ct. at 2283–84.

4 *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 874 (1992).

5 See, e.g., *Stenberg v. Carhart*, 530 U.S. 914 (2000) (holding an undue burden arose from a state law banning partial-birth abortion because it could also apply to dilation and evacuation procedures, one of the more commonly used methods of second-trimester abortions); *Gonzales v. Carhart*, 550 U.S. 124 (2007) (holding no undue burden existed when a law prohibited performing intact dilation and evacuation procedures because it contained an intent element and had sufficiently clear anatomical landmarks to know which procedures were prohibited and which were not); *Whole Woman's Health*, 136 S. Ct. 2292

In *Dobbs*'s wake, states and the federal government are left with a host of questions that they could not approach under *Roe* and *Casey*.<sup>6</sup> One is whether states have the authority to prohibit the use of abortion-inducing drugs within their borders—regardless of whether the Food and Drug Administration (FDA) approves them as safe and effective for use.<sup>7</sup> Immediately following *Dobbs*, the Biden administration anticipatorily issued statements claiming the FDA's regulatory determination of the safety and efficacy of mifepristone (Mifeprex), the only currently approved abortion-inducing drug, preempted state regulations or bans based on contrary state safety and efficacy determinations.<sup>8</sup> While these proclamations evidence the

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(holding an undue burden arose when a law that required abortion providers have local hospital admitting privileges and imposing minimum safety standards for surgical centers); *June Med. Servs.*, 140 S. Ct. 2103 (again finding admitting privileges requirement imposed an undue burden).

6 See, e.g., David S. Cohen, Greer Donley & Rachel Rebouché, *The New Abortion Battleground*, 123 COLUM. L. REV. 1 (2023) (raising questions about extraterritoriality enforcement, federal preemption, medicated abortion, and application of state laws on federal lands); Rachel M. Cohen, *The Coming Legal Battles of Post-Roe America*, VOX (June 27, 2022, 7:30 AM), <https://www.vox.com/2022/6/27/23183835/roe-wade-abortion-pregnant-criminalize> [<https://perma.cc/ZP9A-MJ5L>] (“Can a state punish a resident for getting an out-of-state abortion? Can it punish the provider in another state who facilitated it? . . . ‘Can a State prohibit advertising out-of-state abortions or helping women get to out-of-state providers? Can a State interfere with the mailing of drugs used for medication abortions?’” (quoting *Dobbs*, 142 S. Ct. at 2337 (Breyer, Sotomayor, & Kagan, JJ., dissenting))); Harry Bruinius, *After Roe, Many Questions: Where the Legal Fight Moves Next*, CHRISTIAN SCI. MONITOR (July 12, 2022), <https://www.csmonitor.com/USA/Politics/2022/0712/After-Roe-many-questions-Where-the-legal-fight-moves-next> [<https://perma.cc/6YHB-ETUC>] (“Will residents of states that ban abortion be able to travel to other states for the procedure? . . . Can states ban abortion medication sent via U.S. mail or private courier? . . . How will states enforce bans?”); *What Comes After Roe?*, THE ATLANTIC (July 1, 2022), [https://www.theatlantic.com/politics/archive/2022/07/laws-and-rights-after-roe/661456/?utm\\_source=apple\\_news](https://www.theatlantic.com/politics/archive/2022/07/laws-and-rights-after-roe/661456/?utm_source=apple_news) [<https://perma.cc/5XPT-VTB4>] (raising questions about how enforcement will work and potential state surveillance of mail or period-tracking).

7 Amanda D'Ambrosio, *Is the ‘Abortion Pill’ Restricted by State Bans?*, ABC NEWS (July 1, 2022, 10:43 AM), <https://abcnews.go.com/Health/abortion-pill-restricted-state-bans/story?id=86069230> [<https://perma.cc/D5EA-CQZ9>]; Jamie Kenney, *Can States Ban the Abortion Pill? FDA Rules May Make That Hard*, ROMPER (June 28, 2022), <https://www.romper.com/life/can-states-ban-the-abortion-pill> [<https://perma.cc/37J4-6W5S>].

8 Attorney General Merrick B. Garland Statement on Supreme Court Ruling in *Dobbs v. Jackson Women's Health Organization*, U.S. DEP'T OF JUST. (June 24, 2022), <https://www.justice.gov/opa/pr/attorney-general-merrick-b-garland-statement-supreme-court-ruling-dobbs-v-jackson-women-s> [<https://perma.cc/F4Y4-YWA2>] (“States may not ban Mifepristone based on disagreement with the FDA's expert judgment about its safety and efficacy.”). President Biden publicly highlighted that the FDA had approved mifepristone and promised to ensure continued access to it. President Biden (@POTUS), TWITTER (June 24, 2022, 3:05 PM), <https://twitter.com/POTUS/status/1540425987095203841> [<https://perma.cc/XDR8-FR69>]. The administration is already making good on its promises to expand access to mifepristone, even going as far as dropping the in-person dispensing

administration's stance, they do not resolve the underlying question of whether state mifepristone bans are preempted by FDA approval.<sup>9</sup>

To assess this novel question, Part I surveys the birth of the FDA, Congress's purposes in instituting it, and its approval of mifepristone. Part II examines the current preemption doctrine and uncovers the particularities of its application for federal agency actions and regulations. Part III will look at express, impossibility, obstacle, and field preemption and demonstrate how under current precedent and Congress's discernable purposes, none of them would preempt a state ban on the use of FDA-approved mifepristone. Congress has never expressed a clear intent to expressly preempt any state drug regulations through its grant of power to the FDA. Nor has it shown any clear purpose to equate FDA approval with ensuring approved drugs remain freely accessible to the public; approving a product to be used by the public does not necessarily *require* that that product is freely available on the marketplace. Rather, Congress intended the FDA to prevent unsafe or inefficacious drugs from reaching the market without demanding that those drugs remain easily and freely accessible

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requirements previously imposed and allowing the drug to be dispersed at any certified pharmacy. *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2023), <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation#The%20January%202023%20REMS%20Modification> [<https://perma.cc/P7M7-E5E3>] (“Under the Mifepristone REMS Program, as modified, Mifeprex and its approved generic can be dispensed by certified pharmacies or by or under the supervision of a certified prescriber.”); Spencer Kimball & Bertha Coombs, *CVS and Walgreens Plan to Sell Abortion Pill Mifepristone at Pharmacies After FDA Rule Change*, CNBC (Jan. 5, 2023, 10:43 AM), <https://www.cnbc.com/2023/01/05/abortion-cvs-and-walgreens-will-sell-mifepristone-in-pharmacies.html> [<https://perma.cc/5C27-RQER>]; see also Ahmed Aboulenein, Gabriella Borter & Michael Erman, *Now Able to Sell Abortion Pill, U.S. Pharmacies Weigh if They Should*, REUTERS (Jan. 6, 2023, 2:56 PM), <https://www.reuters.com/business/healthcare-pharmaceuticals/now-able-sell-abortion-pill-us-pharmacies-weigh-if-they-should-2023-01-06/> [<https://perma.cc/A492-KD9H>] (noting that “[l]egal questions are swirling around the prospects of a drug with FDA approval being made illegal under state law in some parts of the country”); Jacqueline Howard, *Some Major Pharmacies Are Planning to Dispense Abortion Pills, But Not in Every State*, CNN HEALTH (Jan. 5, 2023, 12:56 AM), <https://www.cnn.com/2023/01/04/health/fda-abortion-pills-pharmacies-xpn/index.html> [<https://perma.cc/98T5-PNZX>] (noting that the REMS change does not override state abortion bans and that “[i]n the current political climate, ‘it’s far from clear’ whether the US Supreme Court would say the FDA’s recent actions ‘preempt’ state laws restricting access to medication abortion . . . or that state laws are preempted to the extent they regulate medication abortion”).

9 The Congressional Research Service itself does not fully endorse the administration's position, recognizing instead that “a state's ability to restrict or prohibit access to these drugs may depend on the interplay between state and federal law.” JENNIFER A. STAMAN & JON O. SHIMABUKURO, CONG. RSCH. SERV., LSB10706, MEDICATION ABORTION: A CHANGING LEGAL LANDSCAPE 1 (2022).

to the entire market. State bans on FDA-approved drugs do not rise as an obstruction to this congressional objective. Finally, Congress has never granted the FDA the entire field of drug regulation but has instead recognized the existence of concurrent state action in the field. This recognition precludes any possibility that Congress intended the FDA to have exclusive, comprehensive domain over drug regulations. Thus, a state ban on FDA-approved mifepristone would not be preempted by current federal law or regulation.

## I. CONGRESS'S PURPOSE, FDA HISTORY AND APPROVAL PROCESS

To understand how that is so, the FDA's history, purpose, and scope of power provide the starting place to analyze its preemptory power over the drugs it approves. This Part examines the creation of the FDA and how its function has evolved over its lifetime so that Congress's express and nonexpress purposes for the FDA can be understood. Understanding Congress's purpose for the FDA—and the authority Congress granted to carry out its objectives for the FDA—are critical to understanding the extent of the agency's preemptory power, especially over drugs it approves for use as safe and effective. This Part continues by examining the approval process the FDA uses for its drugs is necessary to uncover exactly how state laws and regulations may conflict with FDA requirements, especially ones that arise from the approval and labeling process. Finally, this Part looks specifically to the FDA's approval of mifepristone, what elements of it are vital to determining the contours of FDA preemption of state abortion bans, and how the shift *Dobbs* wrought blows open the realm of reasons a state can point to that do not inevitably contradict FDA determinations.

### A. *Background & Function of the FDA*

Congress gave birth to the FDA in the Pure Food and Drug Act of 1906.<sup>10</sup> The Act prohibited the manufacture, sale, or transportation of “adulterated or misbranded” foods and drugs.<sup>11</sup> Congress fashioned the legislation to carry out its purpose to supplement—and not displace—“the protection for consumers already provided by state regulation and common-law liability.”<sup>12</sup> Rather, the Act allowed the

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10 See Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, ch. 3915, § 4, 34 Stat. 768, 769 (1906) (commonly called the Pure Food and Drugs Act); *When and Why Was FDA Formed?*, U.S. FOOD & DRUG ADMIN. (Mar. 28, 2018), <https://www.fda.gov/about-fda/fda-basics/when-and-why-was-fda-formed> [<https://perma.cc/VZ5H-DPCV>].

11 § 1, 34 Stat. at 768.

12 *Wyeth v. Levine*, 555 U.S. 555, 566 (2009).

federal government to add a layer of “complementary”<sup>13</sup> protection over drug and medical regulations, recognizing that those were fields “which the States have traditionally occupied.”<sup>14</sup> In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (FDCA), in part to allow the FDA to further regulate food and drugs by granting the authority to prohibit the distribution of new drugs until the FDA approved them.<sup>15</sup> Initially, the FDA simply had to prove that the drug was unsafe for distribution, but Congress amended the FDCA in 1962 to require the manufacturer to prove that the drug was safe for distribution.<sup>16</sup> Continuing the complementary relationship between state and federal law in drug regulation, Congress’s 1962 amendments expressly stated that “[n]othing in the amendments . . . shall be construed as invalidating any provision of State law . . . unless there is a direct and positive conflict.”<sup>17</sup> Despite Congress’s incremental expansion of the FDA’s complementary power over drug regulation, it “took care to preserve state law.”<sup>18</sup> In the history giving rise to the FDA, Congress made clear that its purpose and authority were oriented toward consumer protection and allowing concurrent state and federal regulation in that field advanced, and did not impede, that purpose. Never does that consumer protection purpose seem orientated toward the distinguishable purpose of ensuring public access to approved products.

To that end, one of the FDA’s primary functions today is to approve new drugs for use. The FDA’s current approval process for new drugs requires manufacturers to submit a new drug application (NDA) that demonstrates the drug is safe and effective for use, proven with extensive documentation about the drug’s composition and effects.<sup>19</sup> The manufacturer must include the proposed labeling for

13 *Id.* at 578.

14 *See id.* at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)); Stacey L. Worthy, Shrutii R. Kulkarni & Daniel C. McClughen, *The Compounding Conundrum: How Insufficient Delineation of Regulatory Responsibility Has Created a Need for State and Federal Compounding Drug Law Reform*, 72 *FOOD & DRUG L.J.* 506, 508 (2017).

15 Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399i (2018)); *Wyeth*, 555 U.S. at 566.

16 Drug Amendments of 1962, Pub. L. No. 87-781, §§ 102, 104, 76 Stat. 780, 781, 784 (codified as amended at 21 U.S.C. §§ 301–379e (2018)) (amending the Act to now prohibit any distribution of “any new drug” unless an application for that drug was approved and “effective”); *Wyeth*, 555 U.S. at 567.

17 § 202, 76 Stat. at 793.

18 *Wyeth*, 555 U.S. at 567.

19 *See* 21 U.S.C. § 355(a), (b)(1)(A)(i)–(viii) (2018); 21 C.F.R. § 314.50(d)(5)(iv) (2021) (stipulating the detailed contents of an NDA and broadly requiring “any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source”).

the new drug<sup>20</sup> along with a detailed “discussion of why the [drug’s] benefits exceed the risks under the conditions stated in the labeling.”<sup>21</sup> The FDA takes in all of the submitted evidence and decides whether the drug is “safe for use” under the conditions the manufacturer laid out in the proposed label.<sup>22</sup> The FDA will deem the drug safe and effective if its “probable therapeutic benefits . . . outweigh its risk of harm.”<sup>23</sup> Once approved, a manufacturer is expressly prohibited from changing the drug product in any “major” way.<sup>24</sup> Major changes include the “qualitative or quantitative formulation of the drug product,” inactive ingredients, or “specifications provided in the approved NDA.”<sup>25</sup> Compiling and submitting an NDA is a daunting task as each typically “spans thousands of pages and is based on clinical trials conducted over several years.”<sup>26</sup> If approved, the approval represents the agency’s determination that the drug is safe and effective for marketing and distribution. But a mere determination of safety and efficacy at one point in time by one agency “has never been regarded as a *final* stamp of approval of the drug’s safety.”<sup>27</sup> Neither has the FDA’s determination of a drug as merely safe and effective ever been equated to safe, effective, *and* required to be sold.<sup>28</sup>

The FDA’s drug approval process can occur in two different ways. After one version of a new drug gains FDA approval, other manufacturers who produce the same drug may seek approval under an expedited process.<sup>29</sup> Oftentimes, manufacturers of a generic version of a name-brand drug will use this secondary process.<sup>30</sup> Congress created this secondary path to FDA approval in 1984 to help

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20 21 U.S.C. § 355(b)(1)(A)(vi) (2018).

21 21 C.F.R. § 314.50(d)(5)(viii) (2021).

22 21 U.S.C. § 355(d) (2018).

23 *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000).

24 *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 477 (2013).

25 21 C.F.R. § 314.70(b)(2)(i) (2021).

26 *Mut. Pharm.*, 570 U.S. at 476 (citing U.S. GOV’T ACCOUNTABILITY OFF., REPORT TO CONGRESSIONAL REQUESTERS: NEW DRUG DEVELOPMENT (2006), as reprinted in 26 BIOTECHNOLOGY L. REP. 84, 92 (2007)).

27 *Id.* at 499 (Sotomayor, J., dissenting) (emphasis added); see also *id.* (“Under the FDCA, manufacturers, who have greater ‘access to information about their drugs’ than the FDA retain the ultimate responsibility for the safety of the products they sell.” (citation omitted) (quoting *Wyeth v. Levine*, 555 U.S. 555, 578–79 (2009))).

28 See THOMAS JIPPING & SARAH PARSHALL PERRY, THE HERITAGE FOUND., STATES MAY RESTRICT ABORTION DRUGS 12 (2022) (“The fact that an FDA-approved drug *may* be marketed, however, does not mean that it *must* be marketed or *may only* be marketed in the manner that the FDA has approved.”).

29 See 21 U.S.C. § 355(j) (2018).

30 See *The Generic Drug Approval Process*, U.S. FOOD & DRUG ADMIN. (Mar. 17, 2022), <https://www.fda.gov/drugs/news-events-human-drugs/generic-drug-approval-process> [<https://perma.cc/8E87-UQEZ>].

smooth the approval process for drugs that substantively had already undergone rigorous evaluation.<sup>31</sup> Drugs approved by this secondary path must be equivalent to the one previously approved.<sup>32</sup> The generic drug must have the same active ingredient(s) and methods of administration as the brand-name drug.<sup>33</sup> Just as with name-brand drugs, the FDA permits no major changes unless they are pre-approved.<sup>34</sup> Importantly, the second drug must also almost always have the same labeling as the previous drug.<sup>35</sup> Its approval can be revoked if the label or any other major change deviates from the brand-name drug.<sup>36</sup>

Beyond mere approval of a drug as safe and effective, the FDA may impose a Risk Evaluation and Mitigation System (REMS).<sup>37</sup> A REMS is a safety program that the FDA requires for certain drugs that have “serious safety concerns” so that the drug’s benefits can be sure to outweigh its inherent risks.<sup>38</sup> The imposition of a REMS is rare<sup>39</sup>—“only a few medications [even] require a REMS.”<sup>40</sup> One such example is mifepristone, the only FDA-approved drug for terminating a pregnancy.<sup>41</sup> Mifepristone’s REMS provides that it must be dispensed

31 See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 801–871a (commonly known as the Hatch-Waxman Act); *Pliva, Inc. v. Mensing*, 564 U.S. 604, 612 (2011) (the secondary approval process “allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug”).

32 21 U.S.C. § 355(j)(2)(A) (2018).

33 *Id.* § 355(j)(2)(A)(i)–(iv).

34 See *supra* note 24 and accompanying text.

35 21 U.S.C. § 355(j)(2)(A)(v). As explained, whether or not a drug is approved under the first process or the second will govern its labelling regulations which in turn may determine whether state law touching that drug is preempted. Compare *Wyeth v. Levine*, 555 U.S. 555 (2009) (state law not preempted because a name-brand drug may seek labelling adjustments), with *Pliva*, 564 U.S. 604 (state law preempted because a generic drug’s label must match its name-brand counterpart and thus cannot adjust to state requirements).

36 *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 477 (2013) (“[A]pproval for a generic drug may be withdrawn if the generic drug’s label ‘is no longer consistent with that for [the brand-name] drug.’” (alteration in original) (quoting 21 C.F.R. § 314.150(b)(10))).

37 *Risk Evaluation and Mitigation Strategies | REMS*, U.S. FOOD & DRUG ADMIN. (Dec. 17, 2021), <https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-remis> [<https://perma.cc/SCF6-JZBB>].

38 *Id.* The FDA is statutorily required to issue a REMS for any drug that would not have its risks outweighed by its benefits were there no REMS issued. See 21 U.S.C. § 355-1(a)(1) (requiring a REMS if the FDA “determines that a [REMS] is necessary to ensure that the benefits of the drug outweigh the risks of the drug”).

39 A REMS is in place for less than five percent of all FDA-approved drugs. Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627, 640 (2022).

40 U.S. FOOD & DRUG ADMIN., *supra* note 37.

41 *Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/postmarket-drug-safety->

under the supervision of a qualified healthcare provider who only dispenses it after requiring a patient to sign a Patient Agreement Form.<sup>42</sup> The FDA implements and revises these requirements in light of “specific scientific findings” about the drug’s safety and efficacy.<sup>43</sup>

### B. Mifepristone Approval History

The FDA first approved Mifeprex, the name-brand version of mifepristone, in 2000 under suspicious circumstances.<sup>44</sup> In 2016, the FDA approved a supplemental application based on further data submitted by the manufacturer.<sup>45</sup> This approval represents the agency’s determination that Mifeprex (and thus generic mifepristone as well) “is safe and effective when used to terminate a pregnancy in

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information-patients-and-providers/mifeprex-mifepristone-information [https://perma.cc/9RVC-Y5MP].

42 *Id.* Prior to changes made in light of the coronavirus pandemic and the Biden administration’s recent move to allow mifepristone to be dispensed at certified pharmacies, mifepristone was the only drug of all 20,000 FDA-approved drugs that the FDA required to be picked up in-person. *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 579 (2021) (Sotomayor, J., dissenting from grant of application for stay).

43 Cohen, Donley & Rebouché, *supra* note 6, at 53–54.

44 U.S. FOOD & DRUG ADMIN., *supra* note 41. The FDA’s approval occurred under some unusual circumstances. Danco Laboratories, the company which applied for the NDA, was unusually secretive and incorporated in the Cayman Islands. Robert O’Harrow Jr., *Drug’s U.S. Marketer Remains Elusive*, WASH. POST (Oct. 12, 2000), <https://www.washingtonpost.com/archive/politics/2000/10/12/drugs-us-marketer-remains-elusive/8b7b732b-0f23-4c96-9051-714cd3d9f6f8/> [https://perma.cc/5XR6-B5GU]. The FDA typically requires data from two trials that are randomized, blinded, and controlled but neither of the two trials the FDA considered for Mifeprex’s approval were randomized, blinded, or controlled. STAFF OF H. COMM. ON GOV’T REFORM, 109TH CONG., THE FDA AND RU-486: LOWERING THE STANDARD FOR WOMEN’S HEALTH 15–19 (Comm. Print 2006) (congressional report finding the FDA deficiently handled mifepristone’s approval and its post-approval surveillance). Conservative legal advocates have recently filed a lawsuit arguing that the FDA’s approval of mifepristone was improper and illegal. Complaint at 2, *All. for Hippocratic Med. v. FDA*, No. 22-cv-00223 (N.D. Tex. Nov. 18, 2022); *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, ALL. DEFENDING FREEDOM (Feb. 13, 2023), <https://adfmedia.org/case/alliance-hippocratic-medicine-v-us-food-and-drug-administration> [https://perma.cc/Y2DJ-FK3B]. Observers believe that they have a chance of success. Allie Reed & Celine Castronuovo, *Abortion Pill Opponents Seize New Chance to Target FDA Approval*, BLOOMBERG L. (Nov. 23, 2022, 5:25 AM), <https://news.bloomberglaw.com/health-law-and-business/abortion-pill-opponents-seize-new-chance-to-target-fda-approval> [https://perma.cc/YU3X-NWZT] (“Kacsmark will most likely side with the ADF plaintiffs . . . Any appeal of a decision by Kacsmark would head to the US Court of Appeals for the Fifth Circuit, which has 12 judges appointed by Republican presidents out of 16 active judges. From there, the next step is the Supreme Court that threw out *Roe*.”).

45 U.S. FOOD & DRUG ADMIN., *supra* note 41; see U.S. FOOD & DRUG ADMIN., NDA 020687 MIFEPREX (MIFEPRISTONE) TABLETS, 200 MG, RISK EVALUATION AND MITIGATION STRATEGY (REMS) 4 (2016).



accordance with the revised labeling.<sup>46</sup> Mifeprex is only approved, in conjunction with misoprostol,<sup>47</sup> through the first seventy days of pregnancy.<sup>48</sup> Later, in 2019, the FDA approved a generic version of Mifeprex, mifepristone tablets, manufactured by GenBioPro, Inc.<sup>49</sup> After the FDA initially approved Mifeprex, some states seemed poised to ban its sale, setting up the preemption question, but under the obsolete *Roe/Casey* regime.<sup>50</sup> Instead of doing so, states punted and simply passed additional restrictions on Mifeprex.<sup>51</sup> States have long had laws that seemingly conflict with the FDA's determination of mifepristone as safe and effective by going beyond the safety requirements implemented in mifepristone's REMS.<sup>52</sup> But these laws had not been challenged for being in tension with the FDA's REMS requirements. Yet in the lead-up to the Court's *Dobbs* ruling and especially in the aftermath, attention increasingly turned to how stringent state regulations or full bans on abortion are affected by the FDA's approval and regulation. Indeed, even before the Court decided *Dobbs*, GenBioPro brought litigation against Mississippi seeking to enjoin Mississippi's stringent regulation of mifepristone on

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46 *Mifeprex (Mifepristone) Information*, U.S. FOOD & DRUG ADMIN. (Mar. 30, 2016), <http://wayback.archive-it.org/7993/20161022053346/http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111323.htm>, [https://perma.cc/9L8C-WEEG].

47 Misoprostol is required to be used following mifepristone to successfully complete a medication abortion. *Mifepristone (Mifepristone Linepharma) Followed by Misoprostol (GyMiso) for Terminating Early Pregnancy*, NPS MEDICINEWISE (Feb. 16, 2015), <https://www.nps.org.au/news/mifepristone-mifepristone-linepharma-followed-by-misoprostol-gy-miso-for-terminating-early-pregnancy> [https://perma.cc/ZD4U-FNAF]. However, misoprostol is only approved by the FDA for the treatment of gastric ulcers and any use in relation to pregnancy termination constitutes an off-label use. *Off-Label Use: Licensed & Unlicensed Indications*, MISOPROSTOL.ORG, <http://www.misoprostol.org/off-label-use/> [https://perma.cc/RD66-V6BM]. The FDA specifically warns of the risks of its use in relation to labor and delivery and highlights that these are unapproved uses. *Misoprostol (Marketed as Cytotec) Information*, U.S. FOOD & DRUG ADMIN. (July 10, 2015), <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/misoprostol-marketed-cytotec-information> [https://perma.cc/KUU6-M69C].

48 U.S. FOOD & DRUG ADMIN., *supra* note 41.

49 *Id.*; U.S. FOOD & DRUG ADMIN., *supra* note 8; *Putting Access into Practice: Generic Mifepristone Is Here*, GENBIOPRO, <https://genbiopro.com/> [https://perma.cc/DFB9-4FVK].

50 See Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 MICH. ST. L. REV. 1, 18.

51 *Id.*

52 See Cohen et al., *supra* note 6, at 54–55, for a list of various state laws that conflict with the FDA's REMS safety regulations. Some of the state regulations that go beyond the minimums in the REMS include requiring a physician to be present when mifepristone is delivered, requiring in-person counseling or ultrasounds, barring prescription by nonphysician providers, and implementing different timelines for when mifepristone may be provided. *Id.*

preemptory grounds.<sup>53</sup> But after the court requested GenBioPro to explain how the *Dobbs* ruling would affect the litigation,<sup>54</sup> GenBioPro voluntarily dismissed its case.<sup>55</sup> In light of GenBioPro's letter submitted to the court, whether it withdrew its case because of *Dobbs*'s holding is unclear.<sup>56</sup>

### C. *Dobbs's Shift to Rational Basis*

What is clear is that *Dobbs* has completely altered the abortion landscape and how states are permitted to address the issue. *Roe* recognized the Constitution held a hidden right to abortion within an unenumerated right to privacy.<sup>57</sup> The *Dobbs* Court reexamined the Constitution and could no longer find it.<sup>58</sup> The Court underwent an exhaustive historical survey<sup>59</sup> to establish whether abortion rights are "implicit in the concept of ordered liberty" and "deeply rooted in this Nation's history and tradition"<sup>60</sup> and thus in the Fourteenth Amendment's Due Process Clause. It firmly found that "[t]he right to abortion does not fall within this category."<sup>61</sup>

Now, a state law regulating abortion holds a strong presumption of validity and "must be sustained if there is a rational basis on which the legislature could have thought that it would serve legitimate state interests."<sup>62</sup> The Court considered a broad range of interests as legitimate state interests, including "respect for and preservation of

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53 Complaint at 2–3, *GenBioPro, Inc. v. Dobbs*, No. 20-cv-00652 (S.D. Miss. Oct. 9, 2020).

54 See Letter to Judge Wingate in Response to the Court's Inquiry Regarding *Dobbs v. Jackson Women's Health Org.* by GenBioPro, Inc., *GenBioPro, Inc.*, No. 20-cv-00652 (S.D. Miss. June 30, 2022) [hereinafter Letter to Judge Wintergate].

55 Notice of Voluntary Dismissal Without Prejudice at 1, *GenBioPro, Inc.*, No. 20-cv-00652 (S.D. Miss. Aug. 18, 2022); Ian Lopez & Celine Castronuovo, *GenBioPro Gives Up Abortion Pill Suit Against Mississippi*, BLOOMBERG L. (Aug. 19, 2022), <https://news.bloomberglaw.com/health-law-and-business/genbiopro-gives-up-abortion-pill-suit-against-mississippi> [<https://perma.cc/9JM5-4T5V>].

56 See Letter to Judge Wingate, *supra* note 54.

57 *Roe v. Wade*, 410 U.S. 113, 153 (1973) ("This right of privacy . . . founded in the Fourteenth Amendment's concept of personal liberty . . . is broad enough to encompass a woman's decision whether or not to terminate her pregnancy.").

58 *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2279 (2022) ("We therefore hold that the Constitution does not confer a right to abortion.").

59 *Id.* at 2249–56.

60 *Id.* at 2242 (quoting *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997)).

61 *Id.*

62 *Id.* at 2284. Because of this shift, "a court reviewing a medication abortion law . . . may now reach a different conclusion" regarding whether states may restrict how mifepristone is used in contradiction with FDA guidelines. STAMAN & SHIMABUKURO, *supra* note 9, at 2.

prenatal life at all stages of development,” among specified others.<sup>63</sup> Critically, the Court specifically stated that laws that “concern matters of great social significance and *moral* substance” would pass rational basis review.<sup>64</sup> The *Dobbs* Court identified abortion as a “profound moral issue.”<sup>65</sup> That a state may now ban or regulate abortion on a purely moral basis is the inescapable conclusion of the Court’s reasoning; a state’s moral justifications for banning or regulating abortion are not a sufficient basis for striking down that state’s antiabortion action. Before *Dobbs*, states attempted to regulate abortion in a myriad of creative ways to not conflict with the vacuous undue burden standard.<sup>66</sup> But this long game of legislative juggling is over. Abortion advocates will yet challenge state abortion regulations and bans on other grounds. In the case of regulations or bans on mifepristone, preemption may be the most viable foundation from which to launch a challenge. But a close reading of preemption doctrine and precedent reveals this foundation crumbles.

## II. PREEMPTION DOCTRINE & AGENCY APPLICATION

Preemption is a multifaceted doctrine that usually requires a sound examination of its different approaches so as to uncover if federal and state laws are truly in conflict. To do so, this Part lays out the broad strokes of the different preemption doctrines, how the Court currently applies and considers them, and specifically how preemption applies in the context of agency action. Agencies do not have the liberty to override the intents and purposes of Congress. But the difficulty lies in parsing exactly where Congress’s intents and purposes lie. Understanding the doctrines that arise from the Supremacy Clause offers some elusive clarity.

63 *Dobbs*, 142 S. Ct. at 2284 (citing *Gonzales v. Carhart*, 550 U.S. 124, 157–58 (2007)). The Court also included maternal health and safety, the prohibition of “gruesome or barbaric” medical procedures, fetal pain mitigation, and fetal discrimination prohibitions all as legitimate state interests that would survive rational basis review. *Id.*

64 *Id.* (emphasis added).

65 *Id.* at 2240. Abortion poses a “fundamental moral question” that is “ageless.” *Id.* at 2258. The Court identified abortion as a moral question in six different instances. *Id.* at 2240, 2258, 2265, 2284.

66 See Melissa Murray, *The Symbiosis of Abortion and Precedent*, 134 HARV. L. REV. 308, 315 (2020) (describing states as “slowly strangl[ing] access to abortion via a steady stream of restrictions and regulations” following *Casey*). See generally Serena Mayeri, Opinion, *How Abortion Rights Will Die a Death by 1,000 Cuts*, N.Y. TIMES (Aug. 30, 2018), <https://www.nytimes.com/2018/08/30/opinion/brett-kavanaugh-abortion-rights-roe-casey.html> [<https://perma.cc/GMG2-UXFD>] (correctly noting that after *Casey*, many “states have enacted laws that drastically limit access to reproductive health care” but incorrectly implying that the death of constitutional abortion rights would die by 1,000 cuts instead of the one fell swoop that was *Dobbs*).

### A. *Supremacy's Cornerstones & Presumptions*

Federal law is supreme over state law. When federal law comes into tension with state law, as it inevitably will,<sup>67</sup> one must give way. The Constitution requires federal law to win out over, or “preempt,” state law.<sup>68</sup> The state law is displaced and left without effect.<sup>69</sup> The massive overlap between state and federal law means preemption doctrine is one of the most frequently used constitutional law doctrines.<sup>70</sup> The main difficulty in preemption doctrine is ascertaining where federal law and state law are sufficiently in tension so that one must give way. To guide its endeavor, the Court has laid out two “cornerstones” of preemption.<sup>71</sup> “First, ‘the purpose of Congress is the ultimate touchstone in every pre-emption case.’”<sup>72</sup> Second, in every case, but especially where Congress legislated in a field traditionally occupied by states, the Court “start[s] 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 *manifest* purpose of Congress.”<sup>73</sup> Unless Congress has made it clear that it intended to preempt the state, the Court applies a presumption against preemption when dealing with areas states have traditionally regulated.<sup>74</sup> The Court will always apply this presumption against preemption regardless of whether Congress has explicitly spoken on preemption in the area or not.<sup>75</sup> The Court will even scrutinize congressional intent itself through the lens of the

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67 See Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 225 (2000) (“The powers of the federal government and the powers of the states overlap enormously. . . . [N]early every federal statute addresses an area in which the states also have authority to legislate. . . .”).

68 U.S. CONST. art. VI, cl. 2 (“[T]he Laws of the United States . . . shall be the supreme Law of the Land . . . [the] Laws of any State to the Contrary notwithstanding. . . .”).

69 See Nelson, *supra* note 67, at 225–26.

70 Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 768 (1994).

71 *Wyeth v. Levine*, 555 U.S. 555, 565 (2009).

72 *Id.* at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

73 *Id.* (emphasis added) (quoting *Lohr*, 518 U.S. at 485).

74 See *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 518 (1992) (“[W]e must construe [federal agency action] in light of the presumption against the pre-emption of state police power regulations. This presumption reinforces the appropriateness of a narrow reading. . . .”); *La. Pub. Serv. Comm’n v. FCC*, 476 U.S. 355, 369 (1986) (“The critical question in any pre-emption analysis is always whether Congress intended that federal regulation supersede state law.” (emphasis added)).

75 See *Pliva, Inc. v. Mensing*, 564 U.S. 604, 641 (2011) (Sotomayor, J., dissenting) (explaining that the Court applies “this presumption against pre-emption both where Congress has spoken to the pre-emption question and where it has not”).

presumption against preemption, construing congressional intent as preemptive only if that is the only reasonable conclusion.<sup>76</sup>

Congress can intend to preempt state law in several different ways. First, Congress may “expressly” preempt state law in a certain area by including an express preemption clause in a statute.<sup>77</sup> Such a clause withdraws any power from the states to regulate in that area.<sup>78</sup> Express preemption is the least-debated method of preemption because it flows from the Supremacy Clause and is simpler to identify.<sup>79</sup> Whenever possible, the Court will read even express preemption clauses as not preempting state law.<sup>80</sup> In the absence of such a clause, any other federal preemptory power must be implied.<sup>81</sup>

Congress may impliedly preempt state law in two ways: conflict and field. Conflict preemption is analyzed as either obstacle or impossibility preemption. Field preemption occurs when state law regulates a field that Congress “intended the Federal Government to occupy exclusively.”<sup>82</sup> First, obstacle preemption occurs when the effects of a state’s law present an obstacle to the “accomplishment and execution of the full purposes and objectives of Congress.”<sup>83</sup> Obstacle preemption is more vague and indeterminate than other forms of preemption.<sup>84</sup> Because it leaves massive discretion to the judiciary regarding the true effects of a state’s law, Congress’s intent sans an express statement, and whether the state obstructs the federal law, at least one Justice and some scholars scorn obstacle preemption.<sup>85</sup> If not

76 See *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 503 (2013) (Sotomayor, J., dissenting) (highlighting how an inquiry into congressional intent “should be informed by the presumption against pre-emption”).

77 Nelson, *supra* note 67, at 226–27.

78 *Id.*

79 See *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm’n*, 461 U.S. 190, 203 (1983) (“It is well established that within constitutional limits Congress may preempt state authority by so stating in express terms.”); see also *supra* note 68.

80 See *Pliva*, 564 U.S. at 641 (Sotomayor, J., dissenting) (citing *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008)).

81 *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 884 (2000) (“[T]his Court traditionally distinguishes between ‘express’ and ‘implied’ pre-emptive intent . . .”).

82 *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990).

83 *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

84 See Nelson, *supra* note 67, at 228–29.

85 See Ashutosh Bhagwat, *Wyeth v. Levine and Agency Preemption: More Muddle, or Creeping to Clarity?*, 45 TULSA L. REV. 197, 228–30 (2009) (“Thomas argues that the Court should abandon one of the prongs of the Supreme Court’s preemption doctrine, what I call the purpose/obstacle prong, which preempts state law that ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’” (quoting *English*, 496 U.S. at 79)); Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. REV. 559, 623–25 (1997) (“The standard invites the courts to hypothesize and analyze potential situations in which [state law] might stand as an obstacle to or frustrate a congressional purpose. Thus, courts can find obstacles where none exist.”)

construed narrowly, implied obstacle preemption can displace a massive body of state law.<sup>86</sup> The Court constrains obstacle preemption analysis by emphasizing that it “does not justify a ‘freewheeling judicial inquiry into whether a state statute is in tension with federal objectives.’”<sup>87</sup> “[S]uch an endeavor ‘would undercut the principle that it is Congress rather than the courts that pre-empt state law.’”<sup>88</sup> A “high threshold” must be met to achieve obstacle preemption.<sup>89</sup>

Second, impossibility preemption arises when it is a “physical impossibility”<sup>90</sup> to “independently”<sup>91</sup> “comply with both state and federal requirements.”<sup>92</sup> Impossibility preemption is “vanishingly narrow.”<sup>93</sup> The Court will only preempt because of the impossibility of dual compliance when the two laws are on an “inevitable” collision course.<sup>94</sup> Merely claiming a possibility of collision exists will not meet the Court’s demanding standard.<sup>95</sup> Impossibility preemption is traditionally narrow enough to allow one state to completely prohibit activity that is permitted but not required by the federal government.<sup>96</sup>

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(footnote omitted)); Donald P. Rothschild, *A Proposed “Tonic” with Florida Lime to Celebrate Our New Federalism: How to Deal with the “Headache” of Preemption*, 38 U. MIA. L. REV. 829, 854 (1984) (obstacle preemption “permits courts to manipulate the challenged statute’s purpose to achieve the desired result”). See generally E. Travis Ramey, *Congress Hatches the Egg: Justice Thomas’s Textual Mandate Test for Preemption*, 62 ALA. L. REV. 1119 (2011) (examining Justice Thomas’s approach to preemption and his distaste for obstacle preemption).

86 Preemption’s ability to displace massive bodies of state law at the discretion of the judiciary has facilitated a unique union between conservatives, who champion federalism, and liberals, who appreciate stricter state regulation in areas like drug remedies, environmental protections, discrimination, and others. See Nelson, *supra* note 67, at 229 n.16. On the other hand, business interests often advocate for preemption. *Id.* at 229 n.18.

87 Chamber of Com. of the U.S. v. Whiting, 563 U.S. 582, 607 (2011) (quoting *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in the judgment)).

88 *Id.* (quoting *Gade*, 505 U.S. at 111 (Kennedy, J., concurring in part and concurring in the judgment)).

89 *Id.* (quoting *Gade*, 505 U.S. at 110 (Kennedy, J., concurring in part and concurring in the judgment)).

90 *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 143 (1963).

91 *Pliva, Inc. v. Mensing*, 564 U.S. 604, 620 (2011).

92 *Id.* at 618 (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)).

93 Nelson, *supra* note 67, at 228.

94 *Pliva*, 564 U.S. at 634 (Sotomayor, J., dissenting) (quoting *Florida Lime*, 373 U.S. at 143).

95 *Id.* at 635; *Wyeth v. Levine*, 555 U.S. 555, 573 (2009); *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 501 (2013) (“Impossibility pre-emption ‘is a demanding defense’ . . . .” (quoting *Wyeth*, 555 U.S. at 573)).

96 *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678–79 (2019) (first citing *Barnett Bank of Marion Cnty., N.A. v. Nelson*, 517 U.S. 25, 31 (1996); and then citing *Mich. Canners & Freezers Ass’n v. Agric. Mktg. & Bargaining Bd.*, 467 U.S. 461, 478 & n.21 (1984)).

Only “irreconcilable *affirmative* requirements” will conclusively prove Congress’s clear and manifest purpose to preempt state law.<sup>97</sup> Thus, the relevant question for impossibility preemption is whether federal law expressly prohibits or demands activity that state law demands or prohibits, respectively. If one can independently and simultaneously comply with both, then the state law will not be preempted on impossibility grounds.

Finally, field preemption occurs when Congress intends to seize an entire field of regulation by passing regulations that are “so pervasive” that “Congress left no room for the States to supplement it.”<sup>98</sup> The federal interest has to be “dominant”—causing the scheme to suck all the air out of the regulatory room.<sup>99</sup> As with express preemption, “congressional intent to supersede state laws must be ‘clear and manifest’” if Congress is regulating an area traditionally occupied by state law.<sup>100</sup> Field preemption is, in essence, the Court reading an express preemption clause into a statute or regulatory scheme and then determining the scope and validity of such implied clause.<sup>101</sup> These doctrines apply anytime federal law is somehow in tension with state action. When federal agencies in particular promulgate rules or act in contravention of state law, specific doctrines of preemption for agencies apply.

### B. Agency Preemption

Agency actions and regulations may have the force of federal law and can preempt conflicting state laws.<sup>102</sup> But because Congress alone is vested with the legislative power of the federal government,<sup>103</sup> an agency can preempt “state law only when and if it is acting within the

97 *Mut. Pharm.*, 570 U.S. at 501 (Sotomayor, J., dissenting) (emphasis added).

98 *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

99 *Id.*

100 *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

101 *Nelson*, *supra* note 67, at 227. Justice Thomas views field preemption skeptically because of its lack of a textual mandate. *See Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 616–17 (1997) (Thomas, J., dissenting) (“Furthermore, field preemption is itself suspect, at least as applied in the absence of a congressional command that a particular field be pre-empted. Perhaps recognizing this problem, our recent cases have frequently rejected field pre-emption in the absence of statutory language expressly requiring it.”).

102 *Wyeth v. Levine*, 555 U.S. 555, 576 (2009) (first citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000); and then citing *Hillsborough Cnty. v. Automated Med. Lab’ys, Inc.*, 471 U.S. 707, 713 (1985)).

103 U.S. CONST. art. I, § 1 (“All legislative Powers herein granted shall be vested in a Congress of the United States . . .”).

scope of its congressionally delegated authority.”<sup>104</sup> An agency “literally has no power to act, let alone pre-empt the validly enacted legislation of a sovereign State, unless and until Congress confers power upon it.”<sup>105</sup> Any agency claim of preemptory power that Congress has not granted is invalid.<sup>106</sup> Permitting an agency power expansion outside the limits Congress drew would be to bestow the agency with the “power to override Congress,” which the Court has been quite unwilling to do.<sup>107</sup> Because of the intentionally close relationship between the power Congress expressly grants agencies and the reach of their preemptory power, allowing agencies to exercise broad preemptory powers conflicts with safeguards instilled in the Supremacy Clause.<sup>108</sup> Agencies exercise specialized and detailed roles that Congress cannot itself logistically exercise. As a result, courts are strongly tempted to defer to agencies anytime the agency has comprehensively regulated, and its regulations appear conflictual with state law.<sup>109</sup> But such automatic deference “of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence.”<sup>110</sup> Maintaining this balance means that if a statute granting power to an agency is silent, that silence is correctly understood as a limit on the agency’s authority and not an invitation to expand it.<sup>111</sup> The Constitution requires a restrained federal

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104 *New York v. Fed. Energy Regul. Comm’n*, 535 U.S. 1, 18 (2002) (quoting *La. Pub. Serv. Comm’n v. FCC*, 476 U.S. 355, 374 (1986)). Some disagreement exists on whether an agency can expressly preempt state law of its own accord through the rulemaking authority granted by Congress. The Supreme Court has not ever expressly resolved the question but Justices Stevens, Scalia, and Chief Roberts’s dissent in *Watters v. Wachovia Bank, N.A.*, 550 U.S. 1, 22–44 (2007), suggests agencies cannot expressly preempt through their rulemaking authority. Bhagwat, *supra* note 85, at 201. The *Wyeth* Court itself seems to indicate the same. *Wyeth*, 555 U.S. at 576–77 (“[A]gencies have no special authority to pronounce on pre-emption absent delegation by Congress . . .”).

105 *La. Pub. Serv. Comm’n*, 476 U.S. at 374.

106 *See id.*

107 *See id.* at 374–75.

108 See Bradford R. Clark, *Federal Lawmaking and the Role of Structure in Constitutional Interpretation*, 96 CALIF. L. REV. 699, 716 (2008) (“[T]he emergence of broad preemptive lawmaking by administrative agencies pursuant to broad delegations is in substantial tension with the political and procedural safeguards built into the Supremacy Clause.”).

109 Courts will infer preemption simply from the comprehensiveness of a statutory regime and extending that inference to comprehensive regulatory regimes is tempting. The Court recognized this and drew a difference in preemptory inference between statutory and regulatory regimes. *See Hillsborough Cnty. v. Automated Med. Lab’ys, Inc.*, 471 U.S. 707, 717 (1985) (“We are even more reluctant to infer pre-emption from the comprehensiveness of regulations than from the comprehensiveness of statutes.”).

110 *Id.* (citing *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

111 *See* Spencer S. Fritts, Comment, *Perez: A Call for a Renewed Look at Chevron, Jurisdictional Questions, and Statutory Silence*, 40 CAMPBELL L. REV. 173, 183 (2018).



government that cannot override the sovereign power of the states unless demanded by the Supremacy Clause.

Thus, a two-part test parses when agencies may exercise narrow preemptory power.<sup>112</sup> First, the agency must have truly attempted to preempt state law.<sup>113</sup> Second, the agency had to have acted within its statutorily authorized power when it attempted to do so.<sup>114</sup> When examining if an agency truly attempted to preempt state law, a court may not rely simply on “agency proclamations of pre-emption.”<sup>115</sup> The Court merely views these as “musings” that, while informative, are not federal law with preemptive power.<sup>116</sup> Instead, as the *Wyeth* Court did, the judiciary should examine the actual substance of the state and federal law to evaluate whether any conflict truly exists.<sup>117</sup> Doing so requires comparing Congress’s purpose, manifested through an express preemption clause, the accomplishment of a federal objective, impossible dual-compliance, or Congress’s seizing of a field, against the effect of the state action in question.

### III. ANALYSIS

This Part demonstrates how the several preemption doctrines do not preempt state bans on mifepristone despite the FDA approving it as safe and effective for use. It will examine each type of preemption doctrine and relevant precedential cases. Because the Court has never specifically ruled on whether the FDA’s drug approval process would preempt state bans of FDA-approved drugs, the Court’s analogous cases generally deal with the preemption of product liability claims and competing drug-labeling requirements. By examining how state tort claims or drug labeling requirements come into tension with specific elements of the approval process, corollaries can be drawn to how the approval process requirements and FDA determinations may come into tension with a state ban on an approved drug.

Each kind of preemption is analyzed in light of the overarching doctrines of preemption. “First, ‘the purpose of Congress is the ultimate touchstone in every pre-emption case.’”<sup>118</sup> Second, in every

112 Matthew Eslick, *Tension Among Section 307 of the Sarbanes-Oxley Act of 2002*, 17 *C.F.R. § 205.3(d)(2), and State Rules Governing Disclosure of Confidential Client Information*, 53 *DRAKE L. REV.* 133, 156 (2004); see *Fid. Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 154 (1982).

113 Eslick, *supra* note 112, at 156.

114 *Id.*

115 *Wyeth v. Levine*, 555 U.S. 555, 576 (2009).

116 *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1682 (2019) (Thomas, J., concurring).

117 *Wyeth*, 555 U.S. at 576.

118 *Id.* at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

case, but especially where Congress legislates in a field traditionally occupied by states, the Court “start[s] 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 *manifest* purpose of Congress.”<sup>119</sup> Throughout, the Court’s general presumption against preemption will apply in areas where states have traditionally regulated.<sup>120</sup> All congressional intent and statutory provisions are scrutinized through the presumption against preemption.<sup>121</sup>

### A. *Express Preemption Fails*

Express preemption is the clearest category of preemption because it requires an explicit statement from Congress that its “clear and manifest”<sup>122</sup> purpose was to preempt a certain area of state law.<sup>123</sup> When Congress has spoken clearly, the courts’ “task is an easy one.”<sup>124</sup> Nowhere did Congress expressly grant any power to the FDA to preempt state drug regulations in the FDA’s statute, the Federal Food, Drug, and Cosmetic Act.<sup>125</sup>

In all preemption cases, a court first looks at the purpose of Congress.<sup>126</sup> Did Congress ever intend to have the FDA’s determination that a drug is safe and effective preempt any state regulations that may seek to limit or prohibit that drug’s use beyond the FDA’s regulations? To answer that question, the court parses Congress’s intent by examining what it did *not* do.

Congress has never included an express preemption clause for pharmaceuticals throughout the eighty-four-year history of the Federal

119 *Id.* (emphasis added) (quoting *Lohr*, 518 U.S. at 485).

120 See *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 518 (1992) (“[W]e must construe [federal agency action] in light of the presumption against the pre-emption of state police power regulations. This presumption reinforces the appropriateness of a narrow reading . . . .”); *La. Pub. Serv. Comm’n v. FCC*, 476 U.S. 355, 369 (1986) (“The critical question in any pre-emption analysis is always whether Congress *intended* that federal regulation supersede state law.” (emphasis added) (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947))). The regulation of mifepristone clearly falls within a state’s traditional power to regulate health. See Patricia J. Zettler, *Pharmaceutical Federalism*, 92 *IND. L.J.* 845, 869 n.160 (2017) (“[S]tate laws governing pregnancy termination drugs are generally medical practice laws, limiting how practitioners may prescribe the drug.”).

121 See *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 503 (2013) (Sotomayor, J., dissenting).

122 *Wyeth*, 555 U.S. at 565 (quoting *Lohr*, 518 U.S. at 485).

123 See *supra* note 79 and accompanying text.

124 *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990).

125 *Mut. Pharm.*, 570 U.S. at 493 (“[T]he FDCA’s treatment of prescription drugs includes neither an express pre-emption clause . . . nor an express non-pre-emption clause . . . . In the absence of that sort of ‘explicit’ expression of congressional intent, we are left to divine Congress’ will from the duties the statute imposes.”).

126 See *Wyeth*, 555 U.S. at 565 (quoting *Lohr*, 518 U.S. at 485); Grey, *supra* note 85, at 564 (“[C]ongressional intent unquestionably is paramount in a preemption analysis.”).

Food, Drug, and Cosmetic Act. In *Wyeth v. Levine*, the Court walked through the meticulous care that Congress took to not expressly preempt state regulations for FDA-approved drugs.<sup>127</sup> While *Wyeth* does not directly deal with a state expressly banning an FDA-approved drug, it sheds light on the Court’s hesitation to preempt state law unless clearly demanded—even applying the presumption against preemption for implied preemption.<sup>128</sup>

The Court walks through Congress’s intent and purpose over the history of the FDCA. Since the 1930s, Congress “enlarged the FDA’s powers to ‘protect the public health’ and ‘assure the safety, effectiveness, and reliability of drugs.’”<sup>129</sup> Throughout these iterated enlargements of FDA power, the Court notes that Congress nevertheless intentionally “took care to *preserve* state law” and not provide for its preemption.<sup>130</sup> Congress had numerous opportunities to include an express preemption clause. It repeatedly declined to do so.<sup>131</sup>

Congress amended the FDCA in 1962 to require the manufacturer to prove, instead of the FDA to disprove, that a drug was safe and effective.<sup>132</sup> But in the amendments, instead of expressly saying that the FDA’s regulations preempted state law, Congress expressly said that they did not preempt state law save for when there was a “direct and positive” conflict with the FDCA.<sup>133</sup> And following the amendments, per Congress’s express purpose, state suits in tension with FDA regulations “continued unabated despite . . . FDA regulation.”<sup>134</sup> The Court, and lower courts, were repeatedly required to divine when FDA regulations did preempt state regulations and when they did not. Even though Congress knew of the consternation playing out in the judiciary about where to draw the preemptory lines for FDA-approved drugs, Congress *still* took no action to curtail the

127 *Wyeth*, 555 U.S. at 566–67.

128 See Bhagwat, *supra* note 85, at 213 (“[P]rior to the *Wyeth* decision, there was serious doubt about whether the presumption against preemption applied in cases involving implied preemption. The *Wyeth* majority, however, unambiguously holds that the presumption applies to both express and implied preemption, rejecting the dissent’s arguments to the contrary.”).

129 *Wyeth*, 555 U.S. at 567 (quoting Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780, 780 (1962) (codified as amended at 21 U.S.C. §§ 301–79e (2018))).

130 *Id.* (emphasis added).

131 *Id.* at 567–68 (walking through instances of Congress amending the FDCA and never including an express preemption clause—even in light of a spate of state-law suits).

132 *Id.* at 567.

133 *Id.* (quoting § 202, 76 Stat. at 793).

134 *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 340 (2008) (Ginsburg, J., dissenting).

unabated case flow.<sup>135</sup> Rather, Congress amended the FDCA again in 1976—but yet again, not to preempt state regulations of FDA-approved drugs.<sup>136</sup>

Instead, Congress did demonstrate its capability to expressly preempt state regulations by way of the FDCA—it just chose to do it for medical devices and not for pharmaceuticals.<sup>137</sup> By exercising its express preemption power through the FDCA, Congress clearly shows it can intend express preemption for FDA regulations. But it also shows that Congress simply has not ever had the purpose or intent to do so for drug regulations, even in the face of numerous Supreme Court cases dealing with these preemption questions<sup>138</sup> and repeated opportunities to do so. Granting express preemption power to the FDA over medical devices, coupled with Congress’s awareness of the litigation proceeding in the lower courts, “reflects a willingness to allow at least certain types of” tensions between federal regulations and state actions.<sup>139</sup> “Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices.”<sup>140</sup> The *Wyeth* Court notes that even after Levine’s lawsuit, Congress again amended the FDCA but again declined to expressly preempt state drug law or regulation in tension with FDA regulation.<sup>141</sup>

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135 Cf. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–67 (1989) (“The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to ‘stand by both concepts and to tolerate whatever tension there [is] between them.’” (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984))). Congress has not yet necessarily indicated their awareness of state bans on FDA-approved drugs. See Thomas A. Costello, Note, *Quitting Cold Turkey?: Federal Preemption Doctrine and State Bans on FDA-Approved Drugs*, 26 WM. & MARY BILL RTS. J. 839, 857–58 (2018).

136 Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539, 574 (codified as amended at 21 U.S.C. § 360k(a) (2018)).

137 *Id.*

138 See, e.g., *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019); *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013); *Pliva, Inc. v. Mensing*, 564 U.S. 604 (2011); *Wyeth*, 555 U.S. 555 (2009).

139 See Brief for the United States as Amicus Curiae Supporting Petitioner at 21–22, *Mut. Pharm. Co.*, 570 U.S. 472 (2013) (No. 12-142).

140 *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008). “Basic canons of statutory construction counsel that when the legislature includes language in one provision, its exclusion of that language from another is intentional and purposeful.” JIPPING & PERRY, *supra* note 28, at 11 (citing *Statutory Construction*, CORNELL L. SCH., [https://www.law.cornell.edu/wex/statutory\\_construction](https://www.law.cornell.edu/wex/statutory_construction) [<https://perma.cc/UUE4-DK5U>]).

141 See *Wyeth*, 555 U.S. at 567–68 (describing Congress’s amendments as granting power to the FDA to demand a manufacturer change its drug label based on information that may become available after approval and underlining that manufacturers have a duty to update their labels).

When an agency statute is silent, as the FDCA is regarding express preemption for pharmaceuticals, the agency should not always view that silence as a grant of power but often as a limit.<sup>142</sup> When a power-granting statute is silent, the silence can either be construed as Congress’s mere refusal to “tie the agency’s hands” or interpreted as limiting agency discretion.<sup>143</sup> Often, “the silence is better understood as a limit on an agency’s regulatory authority.”<sup>144</sup> In light of Congress’s decades-long refusal to expressly preempt pharmaceuticals through FDA regulation, its silence here should be interpreted as its intent to limit the FDA’s discretion on express preemption. A statute’s declination to interfere with a particular activity indicates that Congress likely intends that activity to be “off-limits from agency action.”<sup>145</sup> Thus, a statute’s silence does not always mean Congress delegated legislative authority to the agency to expand its scope, but rather the silence is better understood as a limit on an agency’s regulatory authority. The federal circuits that have addressed the issue agree that “silence does not always constitute a gap an agency may fill, but often reflects Congress’s decision not to regulate in a particular area at all, a decision that is *binding* on the agency.”<sup>146</sup>

Congress did not grant the FDA the power to expressly preempt state action on pharmaceuticals. Since the 1930s, when the FDCA passed and gave birth to the FDA, Congress has had repeated opportunities to amend the FDCA and grant express preemptory power to the FDA over pharmaceuticals. Repeated pharmaceutical preemption questions at the Supreme Court and lower courts ensured the issue remained salient. But despite amending the FDCA several times and understanding the courts were adjudicating a spate of preemptory questions, Congress never granted the power. Yet, Congress demonstrated its ability to grant express preemption power to the FDA by granting express preemption power to the FDA over medical devices. The repeated congressional declination to grant the FDA express preemption power over pharmaceuticals—despite having

142 See Fritts, *supra* note 111, at 183–84.

143 Or. Rest. & Lodging Ass’n v. Perez, 843 F.3d 355, 360 (9th Cir. 2016) (O’Scannlain, J., dissenting from the denial of rehearing en banc) (quoting Entergy Corp. v. Riverkeeper, Inc., 556 U.S. 208, 222–23 (2009)).

144 Fritts, *supra* note 111, at 183; see also Ry. Lab. Execs.’ Ass’n v. Nat’l Mediation Bd., 29 F.3d 655, 671 (D.C. Cir. 1994), *amended by*, 38 F.3d 1224 (D.C. Cir. 1994) (“Were courts to presume a delegation of power absent an express withholding of such power, agencies would enjoy virtually limitless hegemony, a result plainly out of keeping with *Chevron* and quite likely with the Constitution as well.” (emphasis omitted)).

145 Fritts, *supra* note 111, at 183.

146 *Perez*, 843 F.3d at 362 (O’Scannlain, J., dissenting) (emphasis added). For a list of other circuit cases agreeing with this interpretation of Congress’s silence, see Fritts, *supra* note 111, at 183 n.62.

numerous chances to do so and despite doing it elsewhere in the FDCA—only permits the conclusion that Congress’s silence is meant as a binding of the agency’s hands. Without any express preemption power and in light of Congress’s steadfast refusal to grant it, state prohibitions of mifepristone sale cannot be expressly preempted despite FDA approval. However, state bans may be impliedly preempted if Congress intended the FDA to seize the field of pharmaceutical regulation, the state bans present an obstacle to federal objectives, or it is impossible to comply with both affirmative federal and state law requirements.

### *B. Impossibility Preemption Fails*

Next, compliance with a state ban on mifepristone would not require a violation of federal requirements and thus would not be impliedly preempted through impossibility preemption. Impossibility preemption exists when it is physically impossible to comply with both state and federal requirements simultaneously.<sup>147</sup> “Impossibility preemption is a demanding defense.”<sup>148</sup> Thus a court must examine if federal law expressly prohibits or demands activity that state law demands or prohibits, respectively.<sup>149</sup> If a state bans the use of mifepristone, complying with that ban does not violate any particular federal provision because FDA approval of mifepristone *permits* its sale—it does not *require* it.<sup>150</sup>

No state has yet explicitly sought to ban an FDA-approved drug; they have merely banned particular uses of FDA-approved drugs. Thus, no court has yet examined the question, much less for mifepristone. But the Court has decided four major cases parsing impossibility preemption between FDA pharmaceutical regulations, particularly labeling regulations, and state action that is in tension with those regulations. These cases guide how the Court approaches impossibility preemption for FDA-approved pharmaceuticals that will

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147 See *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019).

148 *Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

149 See *supra* notes 90–97 and accompanying text.

150 See *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 512 (2013) (Sotomayor, J., dissenting) (“Nothing in the language of the FDCA, which is framed as a prohibition on distribution without FDA approval, . . . suggests such a right [to sell a drug free from liability].” (citing 21 U.S.C. § 355(a) (2012))); *Merck Sharp*, 139 S. Ct. at 1681–82 (“Absent a federal statutory right [to sell an approved drug], FDA approval ‘does not represent a finding that the drug . . . can never be deemed unsafe by . . . the application of state law.’” (quoting *Wyeth*, 555 U.S. at 592 (Thomas, J., concurring in the judgment))). No text in the FDCA affirmatively requires anyone to permit the sale of an FDA-approved drug. See Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399i (2018)).

illuminate how the Court will likely answer similar questions should a state ban of an FDA-approved drug reach the Court.

The Court first addressed the issue of impossibility preemption between FDA drug regulations and state tort action in *Wyeth v. Levine*.<sup>151</sup> In *Wyeth*, Diane Levine, a professional musician, received Phenergan, an anti-nausea medication through an IV-push administration.<sup>152</sup> Phenergan's FDA-approved label indicated it should only be injected into a vein and never an artery, because of the risks of gangrene.<sup>153</sup> Levine nevertheless had the drug injected into an artery either by mistake or by a bodily process where a drug can transfer from a vein to an artery, called "perivascular extravasation."<sup>154</sup> This caused irreversible gangrene, resulting in the amputation of her right hand and forearm.<sup>155</sup> Levine brought suit against Wyeth, the drug's manufacturer, claiming Wyeth failed to adequately warn of the danger of gangrene when the drug was administered intravenously through IV push.<sup>156</sup> Levine initially won when a jury concluded that a stronger warning could have prevented the injury from occurring.<sup>157</sup> The Vermont Supreme Court affirmed and the Supreme Court granted certiorari on the preemption question.<sup>158</sup> The question presented was whether "the FDA's drug labeling judgments 'preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use.'"<sup>159</sup>

The Court considered both obstacle and impossibility preemption arguments,<sup>160</sup> but in this analysis, only the Court's reasoning on impossibility preemption is considered. The Court begins by conclusively establishing the two cornerstones of preemption. First, the "purpose of Congress is the ultimate touchstone in every preemption case."<sup>161</sup> And second, for "all preemption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' . . . we 'start with the

151 *Wyeth*, 555 U.S. at 563.

152 *Id.* at 559.

153 Anthony Gostanian, *How the FDA Can Overturn Wyeth v. Levine*, 36 AM. J.L. & MED. 248, 249 (2010).

154 *Id.* at 250.

155 *Wyeth*, 555 U.S. at 558–560.

156 *Id.* at 559–60.

157 *Id.* at 564 ("The trial court proceedings established that Levine's injury would not have occurred if Phenergan's label had included an adequate warning about the risks of the IV-push method of administering the drug.").

158 *Id.* at 563.

159 *Id.* (quoting Petition for Certiorari at i, *Wyeth*, 555 U.S. 555 (2009) (No. 06-1249)).

160 *Id.* at 563–64.

161 *Id.* at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

assumption that the historic police powers of the States were not to be superseded . . . unless that was the clear and manifest purpose of Congress.”<sup>162</sup> As Ashutosh Bhagwat observes, this second cornerstone resolved serious doubt in the preemption jurisprudence about whether the presumption against preemption applied in cases involving implied preemption.<sup>163</sup> After establishing the preemption framework, the Court turns to Wyeth’s impossibility preemption arguments and promptly disposes of them.

When the FDA approves a drug for use, it both approves it for use and approves the exact text on the label.<sup>164</sup> Typically, the FDA requires a supplemental application to make any label changes.<sup>165</sup> A manufacturer of a brand-name drug may unilaterally change a drug’s label in certain ways before receiving FDA approval to do so if it files a supplemental application with the FDA.<sup>166</sup> Wyeth claimed that unilaterally changing the label would have rendered the drug misbranded and violative of federal law.<sup>167</sup> But the Court countered that under the FDCA, simply strengthening a label’s warnings does not render a drug misbranded.<sup>168</sup> Even if it did, the Court explained that the FDA’s *belief* that a drug is misbranded is not conclusive.<sup>169</sup> For the revised label to have been mislabeled in the FDA’s eyes, the FDA would have had to have rejected Wyeth’s unilaterally-revised label when they submitted the changes under the applicable regulation.<sup>170</sup> Only then would there have been a conflict between agency labeling regulations and the duties imposed under state law. The Court explained impossibility preemption would have been met only if there was “clear evidence” that the FDA would have rejected the unilaterally-changed label under the regulation allowing the manufacturer to change the label.<sup>171</sup> However, Wyeth was unable to offer any such evidence<sup>172</sup> and thus “failed to demonstrate that it was impossible for it to comply with

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162 *Id.* (quoting *Lohr*, 518 U.S. at 485).

163 Bhagwat, *supra* note 85, at 213 (citing Ernest A. Young, *Executive Preemption*, 102 NW. U. L. REV. 869, 882–83 (2008) (“arguing that presumption applies only in express preemption cases,” Bhagwat, *supra* note 85, at 213 n.105)).

164 *See supra* notes 19–25 and accompanying text; 21 C.F.R. § 314.105(b) (2023).

165 *Wyeth*, 555 U.S. at 568.

166 21 C.F.R. § 314.70(c)(6)(iii)(A)–(E).

167 *Wyeth*, 555 U.S. at 570.

168 *Id.* (“The FDCA does not provide that a drug is misbranded simply because the manufacturer has altered an FDA-approved label; instead, the misbranding provision focuses on the substance of the label and, among other things, proscribes labels that fail to include ‘adequate warnings.’” (quoting 21 U.S.C. § 352(f) (2006))).

169 *Id.*

170 *See id.* at 571.

171 *Id.*

172 *Id.* at 572.



both federal and state requirements.”<sup>173</sup> The regulation allowing reviewable labeling changes by the manufacturer allowed Wyeth to strengthen their labeling warnings. The simple fact that the FDA held the authority to approve labels did not mean that its ability to approve always foreclosed state requirements that go above and beyond federal ones. Wyeth could comply with the more stringent state requirements and still not be violating any affirmative federal requirement that came about through the approval of the label.

In contrast, the Court found impossibility preemption satisfied in *Pliva, Inc. v. Mensing*<sup>174</sup> when state labeling requirements for a generic FDA-approved drug conflicted with the FDA’s labeling requirements. In *Pliva*, the plaintiffs took the FDA-approved drug metoclopramide (Reglan), and soon developed tardive dyskinesia.<sup>175</sup> They sued the manufacturers of the generic drug under state tort law for failure to provide adequate warning labels about the risk of developing tardive dyskinesia.<sup>176</sup> State tort law required drug manufacturers who were or should have been aware of the risks of their drug to label it in such a way that renders it reasonably safe.<sup>177</sup> However, FDA regulations demanded generic drugs have the exact same labeling as their name-brand counterparts because generic drugs undergo an expedited approval process reliant on the approval process of the name-brand drug.<sup>178</sup> The FDA prohibited any divergence between a generic drug’s label and that of its name-brand counterpart.<sup>179</sup> The plaintiffs argued that FDA regulations permitted the manufacturer to unilaterally modify the label of the generic drug to comply with state tort regulations.<sup>180</sup> However, the Court accepted the FDA’s interpretation that all the avenues of unilateral label change the plaintiffs argued were possible were not viable methods a manufacturer could use to

173 *Id.* at 573.

174 564 U.S. 604 (2011).

175 *Id.* at 610. Tardive dyskinesia is a condition, commonly the side effect of antipsychotic medications, that causes jerky, involuntary movements of the face and body. See *Tardive Dyskinesia*, WEBMD (Dec. 1, 2020), <https://www.webmd.com/mental-health/tardive-dyskinesia> [<https://perma.cc/HGM6-Q67P>].

176 *Pliva*, 564 U.S. at 610.

177 *Id.* at 611.

178 See *supra* notes 29–36 and accompanying text; *Pliva*, 564 U.S. at 613 (“A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name’s.”); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7) (2023).

179 *Pliva*, 564 U.S. at 618 (“Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels.” (citing 21 C.F.R. § 314.150(b)(10))).

180 *Pliva*, 564 U.S. at 613–15.

unilaterally change their drug's label.<sup>181</sup> Because state tort requirements imposed a labeling duty on the generic drug manufacturer that FDA regulations did not permit, it was "impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal-law duty to keep the label the same."<sup>182</sup>

Plaintiffs attempted to argue that if the generic manufacturers had petitioned the name-brand drug manufacturer to submit a label-change application to the FDA, then it was not completely *impossible* to comply with state and federal requirements.<sup>183</sup> But the Court quickly dispatched this argument, explaining that the *possibility* of being able to comply with both federal and state law was insufficient because it would then be "unclear when, outside of express pre-emption, the Supremacy Clause would have any force."<sup>184</sup>

In both *Wyeth* and *Pliva*, the Court interprets impossibility preemption narrowly. In *Wyeth*, the Court found no impossibility preemption because brand-name manufacturers have some label-changing ability even if it is subject to some final FDA approval. But in *Pliva*, generic manufacturers had no such ability. Generic manufacturers could request the brand-name manufacturer to change the label but had little other recourse. Thus, brand-name drug manufacturers do not face impossibility preemption where generic manufacturers do. The Court in both found that a manufacturer could take action to avoid impossibility preemption by adjusting the label. But in neither case did the Court examine whether a manufacturer could take action to avoid impossibility preemption by simply choosing to stop selling a particular drug in a state that had more stringent requirements than federal regulations permitted. In *Pliva*, Justice Sotomayor's dissent alluded to this possible approach, however. Looking at the lower court's decision and *Geier v. American Honda Motor Co.*,<sup>185</sup> Justice Sotomayor recognized that impossibility preemption may be avoided if a manufacturer avoided selling a drug in a particular state.<sup>186</sup> However, because the parties had not argued

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181 *Id.* at 617 ("Federal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels.").

182 *Id.* at 618.

183 *Id.* at 620–21.

184 *Id.* at 619–21 ("This is a fair argument, but we reject it.").

185 529 U.S. 861, 873 (2000) (describing impossibility preemption as occurring when "state law penalizes what federal law requires").

186 *See Pliva*, 564 U.S. at 635 n.8 (Sotomayor, J., dissenting).

the stop-selling theory, Justice Sotomayor did not examine whether that was a viable way to avoid impossibility preemption.<sup>187</sup>

The Court did address the stop-selling theory in its next preemption case for FDA-approved drugs. In *Mutual Pharmaceutical Co. v. Bartlett*,<sup>188</sup> the Court again found that state duties to strengthen label warnings for a generic FDA-approved drug were preempted by the FDA's requirement that generic drug labels exactly match their brand-name counterparts' labels.<sup>189</sup> The lower court had found no preemption because, as it explained, the manufacturer could simply avoid the impossibility of complying with both federal and state law duties by ceasing to sell their drug in that state.<sup>190</sup> But the Supreme Court quickly found a stop-selling rationale to avoid impossibility preemption to be "no solution."<sup>191</sup> It explained that if a "stop-selling rationale" could be adopted for impossibility preemption cases, then "impossibility pre-emption would be 'all but meaningless.'"<sup>192</sup> In all cases of impossibility preemption, the Court explained, the issue could be avoided if the actor facing the conflict "simply ceased acting."<sup>193</sup> The Court highlighted that if this theory were applicable, then even *Pliva* would have been decided incorrectly.<sup>194</sup> Indeed, "the vast majority—if not all—of the cases in which the Court has found impossibility pre-emption, were wrongly decided" if the stop-selling theory is viable.<sup>195</sup>

Justice Sotomayor's dissent, building off of her footnote in *Pliva*, engages the stop-selling theory from the other side. She notes that impossibility preemption exists when two affirmative duties come into conflict—a state imposing some duty that conflicts with some duty Federal law imposes.<sup>196</sup> She explained that the mere avoidance of state

187 *Id.* ("Respondents have not advanced this argument, and I find it unnecessary to consider.")

188 570 U.S. 472 (2013).

189 *Mut. Pharm.*, 570 U.S. at 480, 486 ("Thus, federal law prohibited Mutual from taking the remedial action required to avoid liability under New Hampshire law.")

190 *Id.* at 475 (describing the Court of Appeals' solution as simply pulling "sulindac from the market in order to comply with both state and federal law"); *id.* at 488 ("We reject this 'stop-selling' rationale as incompatible with our pre-emption jurisprudence.")

191 *Id.* at 475.

192 *Id.* at 488 (quoting *Pliva*, 564 U.S. at 621). Professor Lars Noah theorizes that the conservative Justices on the Court lean into the absurdity of the stop-selling theory more from a place of dislike of tort law and not from the absurdity of the theory itself. He thinks that "perhaps those Justices would express greater sympathy for states' rights when positive law comes into conflict with FDA approval." Noah, *supra* note 50, at 34 n.137.

193 *Mut. Pharm.*, 570 U.S. at 488.

194 *Id.* at 488–90.

195 *Id.* at 489.

196 *See id.* at 503 (Sotomayor, J., dissenting) ("But absent a direct conflict between two mutually incompatible legal requirements, there is no impossibility and courts may not

tort liability was not an affirmative duty imposed by the state, but rather an incentive.<sup>197</sup> The manufacturer could choose to risk the liability or stop selling in the state.<sup>198</sup> Neither amounted to a state requirement to violate federal duties. FDA approval of a drug does not require, it only permits, a manufacturer to sell that drug nationwide; further, there is no state-law requirement to modify a label simply because a manufacturer might wish to do so to “avoid or mitigate its exposure to liability.”<sup>199</sup> If, she reasons, there is neither a federal duty to sell nor an affirmative state duty to relabel the drug, then there should be nothing preventing the manufacturer from simply ceasing to sell the drug or, otherwise, continuing to sell the drug and risk whatever liability may arise.<sup>200</sup> Justice Sotomayor’s narrow view of impossibility preemption in this case—examining whether an actor could do *anything* to avoid a conflict—provides clarity to how the majority views impossibility preemption. Justice Sotomayor’s embrace of a stop-selling theory and the majority’s rejection of it offers insight into how the Court may analyze a state ban on mifepristone for impossibility preemption because a state ban may be thought of similarly to a stop-selling argument, even though the two are different.

A state ban on mifepristone would not give rise to impossibility preemption between federal requirements and state prohibitions of the drug. In *Wyeth*, *Pliva*, and *Mutual Pharmaceutical*, the Court never found preemption on impossibility grounds based solely on whether the FDA approved the drug as safe and effective or not. Instead, in

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automatically assume that Congress intended for state law to give way.”); *id.* at 501–02 (“The logic underlying *true* impossibility pre-emption is that when state and federal law impose irreconcilable *affirmative requirements*, no detailed ‘inquiry into congressional design’ is necessary because the inference that Congress would have intended federal law to displace the conflicting state requirement ‘is inescapable.’” (emphasis added) (quoting *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963))).

197 *Id.* at 513 (“New Hampshire’s design-defect cause of action thus does no more than provide an impetus for an action that is permitted and sometimes encouraged or even required by federal law.”).

198 *Id.* at 512 (“It is simply incorrect to say that federal law presupposes that drug manufacturers have a right to continue to sell a drug free from liability once it has been approved. Nothing in the language of the FDCA . . . suggests such a right.”). Justice Sotomayor “emphasized that the receipt of a federal license to market a product did not itself require any particular conduct by the license-holder that might conflict with state law.” Noah, *supra* note 50, at 32.

199 *Mut. Pharm.*, 570 U.S. at 514; *see id.* at 512 (describing the majority’s presumed view that “a manufacturer that received FDA premarket approval has a right not only to keep its drug on the market unless and until the FDA revokes approval, but also to be free from state-law liability that makes doing so more expensive” as “fundamentally inconsistent with the FDCA’s text, structure, saving clause, and history” (citing *Wyeth v. Levine*, 555 U.S. 555, 583 (2009) (Thomas, J., concurring))).

200 *See id.* at 503–15.

*Pliva* and *Mutual Pharmaceutical*, impossibility preemption was met because there was a *specific* provision of the FDA’s regulations that imposed a specific duty concerning drug labeling that compliance with state law would unavoidably violate. In *Wyeth*, the specific FDA labeling regulations existed but were nevertheless satisfiable even if the manufacturer complied with state requirements so that the two did not have to come into full conflict with each other. In *Pliva*, and *Mutual Pharmaceutical*, the specific FDA labeling regulations left no room for manufacturer discretion because they were imposed on a generic drug instead of a name-brand one. The regulations imposed a *specific* duty on the manufacturer that they could not fulfill if they were fully compliant with state regulations and incentives. Yet in all the cases, the specific duty arose because the drugs were FDA approved. Never was mere approval itself sufficient to generate a specific federal duty that would arise in tension with state duties.

If a state were to ban the sale or distribution of mifepristone, no such specific federal regulation is violated if a manufacturer complied with the state ban. Thus, impossibility preemption would be—impossible. Impossibility preemption only exists when state and federal duties or requirements cannot both be accomplished.<sup>201</sup> No rival duties would exist if a state banned mifepristone under current regulations. Justice Sotomayor noted in her *Mutual Pharmaceutical* dissent that “[i]mpossibility does not exist where the laws of one sovereign *permit* an activity that the laws of the other sovereign *restricts* or even *prohibits*.”<sup>202</sup> The FDCA *permits* the nationwide sale of an approved drug. The FDCA does not *require* the nationwide sale of an approved drug.<sup>203</sup> Drug approval is a determination by the federal

201 See *supra* notes 90–97 and accompanying text.

202 *Mut. Pharm.*, 570 U.S. at 502 (Sotomayor, J., dissenting) (emphasis added). The Court affirms this view in a subsequent case. “[W]e have refused to find clear evidence of such impossibility where the laws of one sovereign *permit* an activity that the laws of the other sovereign restrict or even *prohibit*.” *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678–79 (2019) (emphasis added) (citing *Barnett Bank of Marion Cnty., N.A. v. Nelson*, 517 U.S. 25, 31 (1996); *Mich. Cannery & Freezers Ass’n, Inc. v. Agric. Mktg. & Bargaining Bd.*, 467 U.S. 461, 478 & n.21 (1984)).

203 Justice Thomas strongly alludes to this fact in another drug preemption case. “To say, as the statute does, that [a manufacturer] may not market a drug without federal approval . . . is not to say that federal approval gives [a manufacturer] the unfettered right, for all time, to market its drug with the specific label that was federally approved.” *Merck Sharp*, 139 S. Ct. at 1681 (Thomas, J., concurring) (quoting *Wyeth*, 555 U.S. at 592 (Thomas, J., concurring)). He continues by observing that “[a]bsent a federal statutory right to sell a brand-name drug with an FDA-approved label, FDA approval ‘does not represent a finding that the drug, as labeled, can never be deemed unsafe by later federal action, or as in this case, the application of state law.’” *Id.* at 1681–82 (quoting *Wyeth*, 555 U.S. at 592 (Thomas, J., concurring)). Justice Sotomayor highlights the analogy between require and permit in her *Mutual Pharmaceutical* dissent. “[I]f federal law permitted (but did not require) a

government of the safety and efficacy of a drug—not a conferral of a duty to sell that drug nationwide. In short, there is no specific FDA provision that arises contingently to the approval of a drug that a state ban would conflict with. Without rival duties—a state ban on selling drugs that federal law requires to be sold—there can be no impossibility preemption.

The majority's analysis in *Mutual Pharmaceutical*, *Pliva*, and *Wyeth* are not to the contrary. The stop-selling analysis the Court undergoes in *Mutual Pharmaceutical* highlights that manufacturers are under no duty to take drastic, unreasonable action to avoid having state and federal requirements conflict.<sup>204</sup> It does not stand for the proposition that general FDA approval of a drug confers a duty or right to sell that drug nationwide contrary to state views or that refraining from selling a drug would always be too far of an action to avoid preemption. Instead, it merely says that manufacturers need not avoid selling to avoid a conflict. In the case of a state ban on mifepristone, there would be no federal duty to even create potential impossibility preemption. Thus, any discussion of potential actions taken to avoid a potential conflict is not relevant because a conflict cannot occur in the first place.

Because the Court only finds impossibility preemption satisfied for FDA-approved drugs when state requirements come up against specific federal duties, state bans on mifepristone could not be preempted on impossibility grounds because there is no specific federal duty for state bans to conflict with. Impossibility preemption is simpler to analyze because all that is required is to examine if Congress intended for a specific federal duty to exist and then whether a conflictual state duty exists. If so, the state one is preempted. However, obstacle and field preemption questions may not be as clear-cut, especially as it relates to agency actions.

### C. Obstacle Preemption Fails

Next, this Section turns to whether the FDA drug approval process manifests a full purpose and objective of Congress that those drugs be available in interstate commerce such that no state may ban them. Obstacle preemption occurs when a state law's effects present an

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labeling practice that state law prohibited, there would be no irreconcilable conflict . . . [I]mpossibility does not exist where one sovereign's laws merely create an incentive to take an action that the other sovereign has not authorized . . .” *Mut. Pharm.*, 570 U.S. at 502 (Sotomayor, J., dissenting).

<sup>204</sup> See *Mut. Pharm.*, 570 U.S. at 488 (“Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability.” (emphasis added)).

obstacle to the “accomplishment and execution of the full purposes and objectives of Congress.”<sup>205</sup> Obstacle preemption must be construed narrowly otherwise it risks displacing massive portions of state law depending on how the courts exercise the vast judicial discretion inherent in obstacle preemption determinations.<sup>206</sup>

One notable district court case has addressed a state effectively banning an FDA-approved drug. In *Zogenix, Inc. v. Patrick*,<sup>207</sup> a district court preempted a state ban on prescribing and dispensing an FDA-approved drug, Zohydro, because the court found the ban to present an obstacle to federal objectives.<sup>208</sup> After the FDA approved Zohydro on October 25, 2013, Massachusetts Governor Deval Patrick took prompt action prohibiting the use of Zohydro in Massachusetts due to concerns about how it could be misused, especially by opioid addicts.<sup>209</sup> Zogenix, Zohydro’s manufacturer, sought a preliminary injunction, arguing that the ban was preempted by the FDCA.<sup>210</sup> The district court granted the preliminary injunction, ruling that the ban stood as an obstacle to the purpose of the FDCA: making drugs available to promote public health.<sup>211</sup> The court found that Massachusetts’ effective ban “obstruct[ed] the FDA’s Congressionally-given charge” by “interpos[ing] its own conclusion about Zohydro ER’s safety and effectiveness.”<sup>212</sup> But what’s interesting for obstruction preemption purposes is how the court framed the purpose of the FDCA. The court proffered a flawed view of the purpose of the FDCA.<sup>213</sup> As Professor Noah explains, the purpose of the FDCA is just not to ensure that approved drugs are publicly accessible.<sup>214</sup> Rather, it is to “*prevent* the

205 *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); *supra* notes 83–89 and accompanying text.

206 *See supra* note 86.

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

208 *Id.* at \*2 (“When the Commonwealth interposed its own conclusion about Zohydro ER’s safety and effectiveness by virtue of DPH’s emergency order, did it obstruct the FDA’s Congressionally-given charge? I conclude that it did.”).

209 *Id.* at \*1; Noah, *supra* note 50, at 6.

210 Zettler, *supra* note 120, at 872.

211 *See Zogenix, Inc.*, 2014 WL 1454696, at \*2.

212 *Id.*

213 Noah, *supra* note 50, at 2 (describing the court’s preemption analysis here as “seriously flawed”).

214 *Id.* at 8–12 (demonstrating that the FDA is not seeking to ensure public access of approved drugs because the FDCA and its amendments appear to include language preserving state authority, the FDA maintains a stringent approval system, leaves decisions of whether to seek approval to the private sector, imposes no obligation on manufacturers to market approved products, takes no action to ensure affordability, and takes no action to ensure easy access).

introduction of unsafe or ineffective pharmaceutical products.”<sup>215</sup> The *Zogenix* court also used the “aspirational” mission statement of the FDA to provide evidence for its reading of the FDCA’s purpose. The mission statement of the FDA charges it with “promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner.”<sup>216</sup> But no language in this mission statement provides clear evidence that Congress purposed the FDCA to guarantee and protect public access to approved drugs.<sup>217</sup> Instead, it seems to better support that the FDCA was instead meant to prevent unsafe and ineffective drugs from entering the marketplace. In sum, while *Zogenix* is widely cited as evidence that FDA approval preempts state efforts to ban an approved drug, its reasoning is based on a fundamentally flawed analysis of obstacle preemption. It fails to establish that Congress intended and designed the FDA approval process to ensure public access to approved drugs instead of purposing that the FDA approval prevents unsafe and ineffective drugs from public use.

Indeed, the Court’s analysis of obstacle preemption in *Wyeth* points to the opposite. Recall that *Wyeth* analyzed whether a brand-name drug manufacturer could modify an FDA-approved label for a drug. The manufacturer argued that “requiring it to comply with a state-law duty to provide a stronger warning about IV-push administration would obstruct the purposes and objectives of federal drug labeling regulation.”<sup>218</sup> The Court easily found this argument to be “overbroad” and founded on an “untenable interpretation of congressional intent.”<sup>219</sup>

The *Wyeth* Court put to rest the idea that Congress intended the drug approval process of the FDCA to ensure public access to any drugs approved through the process. Instead, Congress enacted the FDCA to “bolster consumer protection against harmful products”—not to ensure public access.<sup>220</sup> The Court explained that the clear and manifest purpose of Congress could not have been to override state law in areas affecting the availability or regulation of approved drugs.<sup>221</sup> If it had been, surely Congress would have enacted an express

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215 *Id.* at 8; see also *Wyeth v. Levine*, 555 U.S. 555, 574 (2009) (“Congress enacted the FDCA to bolster consumer *protection* against harmful products.” (emphasis added) (first citing *Kordel v. United States*, 335 U.S. 345, 349 (1948); and then citing *United States v. Sullivan*, 332 U.S. 689, 696 (1948))).

216 *Zogenix, Inc.*, 2014 WL 1454696, at \*2 (quoting 21 U.S.C. § 393(b)(1) (2012)).

217 See Noah, *supra* note 50, at 9 (the mission statement “hardly supports [the court’s] claim of an overriding federal purpose to promote patient access to approved drugs”).

218 *Wyeth*, 555 U.S. at 573.

219 *Id.*

220 See *id.* at 574.

221 See *id.*



preemption provision when faced with its awareness of state law.<sup>222</sup> Congress’s “silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.”<sup>223</sup> Instead, once the FDA approves a drug and believes any safety concerns are outweighed by perceived benefits, a manufacturer has permission to *market* that drug—not a duty to do so.<sup>224</sup>

Others have argued that the FDA’s imposition of a REMS<sup>225</sup> may represent the FDA’s unique balancing of considerations for a particular approved drug that may not be true for all approved drugs.<sup>226</sup> This unique balancing may evidence more of a federal purpose than merely approving the drug because the FDA institutes an entirely separate level of regulation and oversight for a REMS drug.<sup>227</sup> But the Court in *Wyeth* even seemed to not accept an argument of this sort as contributing to preemption on obstacle grounds. When the manufacturer argued that the drug labeling requirements were a “precise balancing of risks and benefits” that left “no room for different state-law judgments,” quite like the balancing of a REMS would be argued, the Court rejected that approach.<sup>228</sup> In so doing, it recognized that it does not defer to agency proclamations of whether or not a state requirement is preempted.<sup>229</sup> An agency will often frame the federal objective or purpose in such a way that the state regulation is preempted. But while agency views regarding the preemptive effect

222 *Id.* at 575 (“If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA’s 70-year history.”). A California state court recognized this facet of the FDCA, noting that “it would be more accurate to say the Act evidences, far from implied preemption, an instance of implied *non*-preemption.” *Consumer Just. Ctr. v. Olympian Labs, Inc.*, 121 Cal. Rptr. 2d 749, 755 (Cal. Ct. App. 2002).

223 *Wyeth*, 555 U.S. at 575.

224 *JIPPING & PERRY*, *supra* note 28, at 12.

225 See *supra* notes 41–43 and accompanying text for a short discussion of mifepristone’s REMS.

226 See Zettler, *supra* note 120, at 874–75 (hypothesizing that because Zohydro ER had a REMS, it could have provided a plausible obstacle preemption challenge for Massachusetts’s ban on Zohydro ER because “Congress has arguably required the FDA to do a complex balancing of numerous considerations, both in determining whether a REMS is necessary at all, and in determining what to include in a REMS when one is needed”).

227 *Id.* (“In short, through a REMS, the FDA can impose requirements on the drug’s manufacturer that go beyond providing warnings and other information in a drug’s labeling.”).

228 *Wyeth*, 555 U.S. at 575–77.

229 *Id.* at 576 (“[W]e have not deferred to an agency’s *conclusion* that state law is preempted.”). “[A]gency musings, however, do not satisfy the Article I, § 7, requirements for enactment of federal law and, therefore, do not pre-empt state law under the Supremacy Clause.” *Id.* at 587–88 (Thomas, J., concurring).

of its regulations or the objective of the federal government are informative, they are not due full deference.<sup>230</sup> A REMS adds safety regulations to protect the public and balances many considerations to do so. But a REMS does not manifest any congressional purpose to ensure public access to drugs it is imposed on. Instead, a court determines itself if there is actually a clear and manifest purpose or objective of Congress and then whether the state requirement is an obstruction to it or not, using the opinion and expertise of the agency as a guide—not a directive.<sup>231</sup> Because there likely is no clear and manifest purpose from Congress to ensure public access to any drug approved by the FDA, whether or not it has a REMS, the FDA does not have power on obstruction grounds to preempt state requirements or even bans. Congress has never granted the FDA any express preemption power over approved drugs, and has even implicitly said, in amendments to the FDCA, that it “did not intend FDA approval decisions to preempt state bans on any theory other than impossibility.”<sup>232</sup>

Even if there were a congressional purpose to ensure public access to approved FDA drugs,<sup>233</sup> it is unclear that state bans of particular uses

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230 *Wyeth*, 555 U.S. at 576 (The Court does not rely on “agency proclamations of pre-emption.”).

231 *Id.* at 576–77 (“While agencies have no special authority to pronounce on pre-emption absent delegation by Congress, they do have a unique understanding of the statutes they administer . . .”).

232 Zettler, *supra* note 120, at 868.

233 Even if FDA approval of drugs means Congress intended to guarantee public access to that drug, an argument can be made that that may not be the case for mifepristone, specifically. The Comstock Act, sweeping legislation prohibiting the mailing of every “obscene, lewd, lascivious, indecent, filthy or vile article, matter, thing, device, or substance,” is still good law, though largely unenforced. 18 U.S.C. § 1461 (2018); see Ian Millhiser, *The Coming Legal Showdown over Abortion Pills*, VOX (Jan. 22, 2023, 8:00 AM), <https://www.vox.com/policy-and-politics/2023/1/22/23539363/abortion-medication-mifepristone-supreme-court-pills-comstock-matthew-kacsmark> [https://perma.cc/N3UU-QMZA]. Section 1461 would explicitly prohibit the mailing of abortion drugs, including mifepristone. 18 U.S.C. § 1461 (prohibiting the mailing of “[e]very article or thing designed, adapted, or intended for producing abortion”). Ensuring a narrow interpretation and enforcement of the Comstock Act, the Office of Legal Counsel advised the Postal Department’s General Counsel that the Comstock Act does not prohibit mailing “mifepristone or misoprostol where the sender *lacks the intent* that the recipient of the drugs will use them unlawfully.” Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions, 46 Op. O.L.C., slip op. at 1–2 (Dec. 23, 2022), <https://www.justice.gov/olc/opinion/file/1560596/download> [https://perma.cc/2UH5-D8YT] (emphasis added). But this reading of the Comstock Act is certainly not conclusive and does not preclude future administrations from interpreting, and enforcing it, differently than the Biden DOJ. See Ed Whelan, *Unreliable OLC Opinion on Mailing of Abortion Drugs—Part I*, NAT’L REV. (Jan. 4, 2023, 4:09 PM), <https://www.nationalreview.com/bench-memos/unreliable-olc-opinion-on-mailing-of-abortion-drugs/> [https://perma.cc/Q7CE-S4FD] (explaining that “those who are considering mailing abortion drugs should not have

for a drug on grounds other than safety and efficacy would be preempted. The FDA considers a wide range of safety and efficacy data when it makes its approval decision.<sup>234</sup> But it does not routinely consider or balance other interests, especially non-scientific ones. A state may have other interests beyond safety and efficacy that it desires to vindicate. Indeed, a state's interests when it considers medicated abortion regulations or bans are likely to be primarily moral and unrelated to the safety and efficacy of mifepristone or any other potential abortion medication. For a state action to be a true obstruction to the purposes of Congress, it must materially contradict those same purposes. Even if the outcome of a state banning or severely regulating an FDA-approved drug would be the same regardless of the reasoning behind the state's action, if it did so for purposes different than the federal government's purposes such that there is no tension between the two, the state action may not rise as a challenge to congressional purposes. Even Attorney General Garland seems to implicitly recognize this distinction in his statement following *Dobbs*, explaining that state bans on mifepristone would be preempted by FDA approval to the extent they are "based on disagreement with the FDA's expert judgment about its safety and efficacy."<sup>235</sup> This naturally leaves open the question of whether states may not be preempted if they ban mifepristone based on other grounds. Professor Catherine Sharkey, one of the nation's leading federal preemption experts,<sup>236</sup> hypothesized about the interests behind a state drug ban, saying:

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confidence that OLC gets it right, and they would be fools to rely on it"). The scope and enforcement of the Comstock Act is far beyond the scope of this Note but should be explored. For further analysis from Ed Whelan on the errors of the OLC's interpretation, see Ed Whelan, *Unreliable OLC Opinion on Mailing of Abortion Drugs—Part 2*, NAT'L REV. (Jan. 5, 2023, 3:02 PM), <https://www.nationalreview.com/bench-memos/unreliable-olc-opinion-on-mailing-of-abortion-drugs-part-2/> [<https://perma.cc/WG2R-P2BK>]; Ed Whelan, *Unreliable OLC Opinion on Mailing of Abortion Drugs—Part 3*, NAT'L REV. (Jan. 6, 2023, 10:26 AM), <https://www.nationalreview.com/bench-memos/unreliable-olc-opinion-on-mailing-of-abortion-drugs-part-3/> [<https://perma.cc/6XYJ-D74Y>] ("There is no meaningful support for OLC's claim that the federal ban on mailing abortion drugs (section 1461) does not apply when 'the sender lacks the intent that the recipient of the drugs will use them unlawfully.' . . . What possible sense does such a stringent intent test make?" (quoting Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions, slip op. at 1–2)).

<sup>234</sup> See *supra* note 22 and accompanying text.

<sup>235</sup> See Press Release, Merrick B. Garland, Att'y Gen., Dep't of Just., Statement on Supreme Court Ruling in *Dobbs v. Women's Health Organization* (June 24, 2022), <https://www.justice.gov/opa/pr/attorney-general-merrick-b-garland-statement-supreme-court-ruling-dobbs-v-jackson-women-s> [<https://perma.cc/RUN4-9L3W>].

<sup>236</sup> Catherine M. Sharkey, N.Y.U. LAW, <http://its.law.nyu.edu/facultyprofiles/index.cfm?fuseaction=profile.overview&personid=26965> [<https://perma.cc/CU4P-SEXC>].

[S]uppose that the state enacted a ban on a painkiller drug not due to health and safety concerns, but instead because it wanted to recognize and encourage its citizens' puritan-minded, "buck-up in the face of pain" mentality. In such a case, the purpose behind the federal regulations would be different from the state's motivation for action, and the FDA ostensibly would not have considered the state's (non-health and safety) related purposes when regulating. When federal and state actors regulate for different purposes, such that a federal agency is less likely to have considered a state's purported interests, the case for preemption is weaker.<sup>237</sup>

After *Dobbs*, this vindication of other interests concerning abortion without federal interference is what the Court permitted.<sup>238</sup> Now, states can regulate abortion only subject to rational basis review.<sup>239</sup> This broadening of permitted state interests, explicitly extending to even moral and other non-health and safety interests, weakens the case of obstruction preemption if a state bans mifepristone. This is particularly true because there is no clear and manifest federal purpose or objective that would be violated by a state mifepristone ban.

A state ban on mifepristone would not be preempted on obstruction grounds because the FDA approved mifepristone as safe and effective. There is no clear purpose of Congress that a state ban would be obstructing as the FDCA expresses no clear preemptory language over state action unless there is impossibility conflict and further because the FDCA is not intended to ensure nationwide public access to approved drugs.<sup>240</sup> Rather it is merely meant to ensure harmful products do not enter into public use. Even if there were a federal purpose that a state ban would obstruct, the weakness of obstruction preemption in general,<sup>241</sup> combined with *Dobb's* recognition that a whole host of state interests regarding abortion can now be vindicated subject only to rational-basis review, means that a state ban may still not be preempted on obstruction grounds.

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237 Catherine M. Sharkey, *States Versus FDA*, 83 GEO. WASH. L. REV. 1609, 1628 n.85 (2015).

238 See *supra* note 62 and accompanying text.

239 See *id.*; see also STAMAN & SHIMABUKURO, *supra* note 9, at 2 ("Abortion restrictions will now be evaluated under a rational basis review . . . . Applying rational basis review, a court might conclude that a law prohibiting the use of mifepristone in ways that contravene FDA protocol is rationally related to a legitimate government interest . . . .").

240 See JIPPING & PERRY, *supra* note 28, at 15 ("Both the Supreme Court and state courts examining the question have characterized Congress' purpose as, in effect, the opposite of preemption.").

241 See *supra* note 85 and accompanying text; Nelson, *supra* note 67, at 304 ("[T]he modern doctrine of 'obstacle' preemption has no place as a doctrine of constitutional law. . . . The general doctrine of obstacle preemption must therefore give way to a more careful analysis of the rules established by the particular federal statute in question.").

#### D. *Field Preemption Fails*

Much like obstruction preemption, field preemption relies on the showing of a clear congressional purpose. But the congressional purpose must be to seize an entire field of regulation under federal purview.<sup>242</sup> Congress can manifest this intent to seize an entire field of regulation by enacting regulations so pervasive that no room for state regulation remains.<sup>243</sup> Congress sucks all of the air out of the proverbial regulatory room.

Such seizure was not Congress's intent with the FDCA. Drug and medical regulations are generally a "field which the States have traditionally occupied."<sup>244</sup> However, Congress could have intended to seize the entire field of drug regulation if it had so desired. Instead, the FDCA explicitly recognized the coexistence of state law and federal law in this field.<sup>245</sup> The *Wyeth* Court recognized that when Congress passed the FDCA, it understood that state law would still play a role in the field of drug regulation because "Congress did not provide a federal remedy for consumers" hurt by drugs in the original statute nor any subsequent amendments.<sup>246</sup> Again, Congress could have seized the field by saying so, or by adding an express preemption provision to the FDCA. It did neither. Instead, when it amended the FDCA, it only allowed for direct impossibility preemption.<sup>247</sup> In its silence, Congress left the field open and unoccupied by exclusive federal regulation.

The Court summarized its previous precedents in *Merck Sharp* and explicitly found that field preemption over drug regulation is not viable. "[L]anguage, history, and purpose all indicate that 'Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.'"<sup>248</sup> Merely granting some power over a field to an agency does not grant the exclusive domain of that field to

242 See *supra* notes 98–101 and accompanying text.

243 *Id.*

244 *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (quoting *Medtronic, Inc., v. Lohr*, 518 U.S. 470, 485 (1996)); Worthy et al., *supra* note 14, at 508.

245 *Wyeth*, 555 U.S. at 577 (describing the "decades of coexistence" between FDA drug regulations and state law).

246 *Id.* at 574.

247 *Id.* at 574–75 ("[Congress's] silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is *powerful* evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." (emphasis added)).

248 *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1677 (2019) (quoting *Wyeth*, 555 U.S. at 574–75).

the agency.<sup>249</sup> That implication is categorically rejected.<sup>250</sup> Neither does a comprehensive system of regulation necessarily seize an entire field of regulation, as the Court has ruled in other FDA regulations contexts.<sup>251</sup> When Congress is *aware* of state regulations in a field and takes steps to avoid preempting those state regulations except in cases of impossibility preemption, then the “case for federal pre-emption is particularly weak.”<sup>252</sup> Because discerning a congressional intent to seize the field of drug regulation is incredibly difficult, others have recognized that “a field preemption argument is unlikely to be successful because of courts’ reluctance to conclude that Congress implicitly reserved the entire field of drug regulation for the federal government.”<sup>253</sup> If Congress did not clearly intend to seize the field,<sup>254</sup> then a state ban on mifepristone cannot conflict with federal law on field preemption grounds.

### CONCLUSION

*Dobbs v. Jackson Women’s Health Organization* unleashed a new dawn of state regulation over abortion.<sup>255</sup> Before, states were constrained in how they could vindicate their interests through the judicial seizure of abortion law, and today, their interests can be vindicated just as any others may be. However, this new horizon of state power carries questions on how it may interact with existing federal laws and regulations. In particular, states may seek to ban medication abortion. Mifepristone is the only FDA-approved drug to terminate a pregnancy. States that ban abortion or that ban mifepristone, in particular, may face challenges that claim the FDA’s approval of a drug for use as safe and effective preempts states from banning that drug for use.

Those challenges should fail. Preemption only is justified if a clear and manifest purpose or statutory provision of Congress is

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249 See *Ry. Lab. Execs.’ Ass’n v. Nat’l Mediation Bd.*, 29 F.3d 655, 670 (D.C. Cir.), amended by 38 F.3d 1224 (D.C. Cir. 1994).

250 *Id.*

251 *Hillsborough Cnty. v. Automated Med. Lab’ys, Inc.*, 471 U.S. 707, 716 (1985) (“We reject the argument that an intent to pre-empt may be inferred from the comprehensiveness of the FDA’s regulations . . .”).

252 *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–67 (1989) (“The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest and has nonetheless decided to ‘stand by both concepts and to tolerate whatever tension there [is] between them.’” (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984))).

253 Zettler, *supra* note 120, at 874.

254 *Hillsborough Cnty.*, 471 U.S. at 714 (“The question whether the regulation of an entire field has been reserved by the Federal Government is, essentially, a question of ascertaining the intent underlying the federal scheme.”).

255 See *Dobbs v. Jackson Women’s Health Org.*, 142 S. Ct. 2228, 2242–43 (2022).

challenged by a state's laws or regulations. It is not justified anytime states and the federal government regulate concurrently. Preemption can take four different forms: express preemption, impossibility preemption, obstacle preemption, and field preemption. None would preempt a state banning an FDA-approved drug, in particular, mifepristone.

Congress has conscientiously avoided implementing an express preemption clause in the FDCA, the FDA's statute granting it its authority. Without an express preemption clause, the FDA has been granted no power to expressly preempt any state law and can only do so under other preemption approaches.

Impossibility preemption cannot preempt a state ban on mifepristone because the FDCA confers no explicit right or duty on drug manufacturers to ensure their product is freely available to the public. Without a clear congressional purpose that the FDA approving a drug means that that drug should always be publicly accessible, there is no federal duty that is directly conflicting with a state ban. Without a federal duty, it is fully possible to comply with both federal and state requirements, foreclosing any possibility that impossibility preemption would bar a state from banning mifepristone.

Neither does obstacle preemption suffice. Under the Court's obstacle preemption precedents, no clear and manifest purpose of Congress to ensure public access to approved drugs is present. Rather, Congress meant FDA approval to restrict harmful and inefficacious drugs from the market. A state ban on mifepristone cannot rise as an obstacle because Congress advanced no federal objective to have FDA approval equate to nationwide, unfettered public access to the approved drug.

Finally, field preemption suffers the same fate. There is no clear congressional intent that the FDA's drug regulations were to seize the entire field of drug regulation and bar state efforts at regulation. Indeed, Congress enacted the FDCA and its subsequent amendments with the obvious knowledge that state law was to regulate the drug field concurrently.

None of the approaches to preemption meet the bar to preempt a state ban on mifepristone, particularly because a state would be regulating in a traditional area and vindicating interests that the federal government may not have considered during the FDA's approval process. Without any viable route to preempt a state ban on mifepristone, states are free to ban it, pending other federal action to the contrary that may introduce preemption problems. *Dobbs* gave rise to many questions and the answers to most remain unknown. But whether a state may ban FDA-approved mifepristone is not among them.

