Federal Preemption and the Post-*Dobbs* Reproductive Freedom Frontier

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ABSTRACT

In the wake of the *Dobbs* decision abolishing the constitutional right to reproductive freedom, some states have enacted measures that would prohibit the importation, sale, and use of U.S. Food and Drug Administration (FDA)-approved drugs (both prescription and OTC) that are part of medication abortion and emergency contraception medical treatments. Opponents of such measures have raised the prospect of federal preemption under the Federal Food, Drug, and Cosmetic Act (FDCA) in opposition to those enactments.

This paper discusses the two types of implied preemption that would be raised against state bans and other restrictions of FDA-approved abortion-related prescription drugs, as well as possible express preemption in the context of OTC drugs. It examines prior preemption litigation involving affirmative state bans imposed against FDA-approved products. It also addresses implied preemption under *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013), of privately brought "stop-selling" claims brought against various FDA-approved prescription drugs in the product liability context. The paper also discusses state control over medical practice in the context of off-label use of FDA-approved drugs to terminate pregnancy or to provide post-coitus contraception.

The paper concludes that these preemption arguments appear meritorious in the context of actual or de facto state bans on abortion-related drugs, at least in the context of on-label use, with state control over off-label use being a weaker case. It points out that these preemption arguments also place FDA at greater risk of political and judicial interference with its science-based standards for approval of drugs and their intended uses.

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I. INTRODUCTION

After almost fifty years, abortion is no longer a constitutional Due Process right.[1] The post-*Dobbs* era is becoming the next new legal battlefield, with providers already experimenting with ways to broaden access in states where the legal walls begin to close in and restrict access to abortion care.[2]

Federal preemption due to conflict with the Federal Food, Drug, and Cosmetic Act (FDCA)[3] and its predecessors has established roots in American case law going back over a century.[4] The FDCA guarantees market access for safe and effective medications,[5] but without a constitutional right to reproductive freedom, many states have imposed restrictive regulations that seek to govern the U.S. Food and Drug Administration (FDA)-approved drugs used for medication abortion.[6] What happens next requires a balancing between the Supremacy Clause[7] and a state's right to regulate medical care within its borders. Without the constitutional protections that existed under *Roe v. Wade*,[8] "preemption may take on an increasingly prominent role in combatting state laws designed to limit reproductive rights by, at least in part, limiting the use of medical products on the market pursuant to FDA decisions."[9]

The Constitution's Supremacy Clause has been described as "[t]he wellspring of preemption doctrine[.]"[10] The Supremacy Clause states that:

> [t]his Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.[11]

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[1] Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2284 (2022) ("The Constitution does not prohibit the citizens of each State from . . . prohibiting abortion.").

[2] Pam Belluck, *Abortion Pill Providers Experiment with Ways to Broaden Access*, N.Y. TIMES (Sept. 3, 2022), https://www.nytimes.com/2022/09/03/health/abortion-pill-access-roe-v-wade.html?smid=nytcore-ios-share&referringSource=articleShare.

[3] 21 U.S.C. §§ 301–399h (2021).

[4] McDermott v. Wisconsin, 228 U.S. 115, 136–37 (1913); Savage v. Jones, 225 U.S. 501, 529–31 (1912). *See* United States v. Sullivan, 332 U.S. 689, 698 (1948) (applying *McDermott* to prescription drugs).

[5] 21 U.S.C. §§ 355-1(f)(5), 356(d); *cf.* 21 U.S.C. § 360i(f) (similar access issues for medical devices).

[6] *See* David S. Cohen, Greer Donley & Rachel Rebouché, *The New Abortion Battleground*, 123 COLUM. L. REV. 1, 7–10 (2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4032931 (describing how generalized abortion bans may interact with availability of FDA-approved medications that facilitate abortion); Peter Grossi & Daphne O'Connor*, FDA Preemption of Conflicting State Drug Regulation and the Looming Battle Over Abortion Medications*, Nov. 1, 2022, at 31–44, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4258890.

[7] U.S. CONST. art. VI, cl. 2.

[8] Roe v. Wade, 410 U.S. 113 (1973).

[9] Eric Alexander, *Dobbs Would Likely Have Significant Impacts on Drug and Device Companies*, DRUG & DEVICE L. BLOG (June 2, 2022), https://www.druganddevicelawblog.com/2022/06/dobbs-would-likely-have-significant-impacts-on-drug-and-device-companies.html.

[10] Ass'n of Taxicab Operators USA v. City of Dall., 720 F.3d 534, 537 (5th Cir. 2013).

[11] U.S. CONST. art. VI, cl. 2. *See* McCulloch v. Maryland, 17 U.S. 316, 405 (1819) ("The government of the United States, then, though limited in its powers, is supreme; and its laws, when made in the pursuance

Final FDA actions, like approval of a drug and imposition of conditions on its safe and effective use, constitute binding federal law with preemptive effect on conflicting state laws.[12]

There are two main types of preemption: "express preemption in accordance with a statutory or regulatory provision, and implied preemption based on conflict between state and federal law."[13] Implied preemption exists whenever state and federal regulation is incompatible.[14] Conflict preemption, a type of implied preemption, occurs either when compliance with both federal and state law simultaneously would be impossible[15] or when compliance with state law would interfere with the intended operation of federal law, otherwise called "obstacle" preemption.[16] When a state law requirement diverges from what federal law mandates, "state law is nullified to the extent that it actually conflicts with federal law."[17]

Because *Dobbs* removed constitutional Due Process restraints on state power to prohibit abortion, many states have passed laws so doing, or, short of complete prohibition, restricting abortion access with a variety of exceptions.[18] One result is an increasing number of patients looking to out-of-state providers to obtain prescription medication to end a pregnancy.[19] FDA has determined the medications used to do so,

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of the constitution, form the supreme law of the land, any thing in the constitution or laws of any State to the contrary notwithstanding.") (internal quotation omitted).

[12] Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1679 (2019).

[13] JAMES BECK & ANTHONY VALE, DRUG & MEDICAL DEVICE PRODUCT LIABILITY DESKBOOK, § 5.01 (L.J. Press & Supp. 2021).

[14] Another kind of implied preemption is "field preemption," which "occurs when federal law occupies a 'field' of regulation so comprehensively that it has left no room for supplementary state legislation." Murphy v. Nat'l Collegiate Athletic Assn., 138 S. Ct. 1461, 1480 (2018) (citation and quotation marks omitted). The FDCA has not been interpreted that broadly. *E.g.*, GenBioPro, Inc. v. Sorsaia, No. CV 3:23-0058, 2023 WL 5490179, at *9 (S.D.W. Va. Aug. 24, 2023) (*Sorsaia*) (mifepristone REMS do not preempt state law prohibiting doctors from performing abortion; uncodified 1962 savings clause precludes field preemption).

[15] *See* Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 487 (2013) ("Even in the absence of an express pre-emption provision, the Court has found state law to be impliedly pre-empted where it is 'impossible for a private party to comply with both state and federal requirements'") (quoting English v. Gen. Elec. Co., 496 U.S. 72, 79, 110 (1990)); Felder v. Casey, 487 U.S. 131, 138 (1988) ("[T]he relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield.") (internal quotation omitted).

[16] When a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress[,]" the law will be preempted. Wyeth v. Levine, 555 U.S. 555, 589 (2009) (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

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

[18] *See, e.g.*, IDAHO CODE § 18-622; MISS. CODE ANN. §§ 41-41-101, *et seq*. (2016), 15 MISS. ADMIN. CODE § 16-1-44.1. *See generally An Overview of Abortion Laws*, GUTTMACHER INST., https://www.guttmacher.org/state-policy/explore/overview-abortion-laws (summary of state abortion laws).

[19] *See* Cohen et al., *supra* note 6, at 10–17 (describing options to access abortion in states which heavily restrict or ban the procedure, with a focus on medication abortion).

primarily mifepristone,[20] are safe and effective for that use.[21] It has approved such drugs for medication abortions pursuant to the agency's mandate to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner."[22] Other drugs, notably misoprostol, are used in connection with medication abortions.[23]

Immediately after the Supreme Court overturned *Roe*, legal and practical confusion ensued regarding the contours of federal versus state authority in this context.[24] This Article discusses FDCA-related federal preemption and seeks to clarify its application to post-*Dobbs* state-law medication abortion restrictions by addressing the legal boundaries between federal and state law governing access to FDA-approved drugs. Part II discusses implied obstacle preemption, which forms the basis for challenges to state regulation that interferes with access to FDA-approved abortion-related drugs. Part III examines preemption litigation involving state common law bans asserted against FDA-approved products in product liability litigation, particularly the implied preemption of "stop-selling" claims involving FDA-approved prescription drugs. Against this backdrop, Part IV compares the power of states to regulate off-label use of FDA-approved medication and the practice of medicine within its borders with FDA authority over drug approval, marketing, and distribution.

This Article posits that preemption arguments appear meritorious in response to state bans of abortion-related drugs, particularly in the context of on-label use, with state control over off-label use being a weaker case. However, an overly expansive application of FDCA preemption is likely to place FDA at greater risk of political interference with its science-based standards for approval of drugs and their labeling

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[20] Mifepristone (also known as RU-486 or Mifeprex) blocks the body's own progesterone, a hormone needed to sustain a pregnancy; misoprostol (taking twenty-four to forty-eight hours later) causes the uterus to empty, a process similar to an early miscarriage. RU-486 was developed in the 1980s and safely used in Europe since 1987 and in the United States since 2000. *See The Abortion Pill*, PLANNED PARENTHOOD, https://www.plannedparenthood.org/learn/abortion/the-abortion-pill.

[21] In 2000, FDA approved mifepristone for early nonsurgical abortion. Currently, its approved intended use is for use up to ten weeks of gestational age. *See Medication Abortion*, GUTTMACHER INST., https://www.guttmacher.org/state-policy/explore/medication-abortion#. In 2016, FDA approved mifepristone for use in combination with another widely used drug, Misoprostol. *See* Christine Vestal, *Abortion Medications Set to Become Next Legal Battlefield*, STATELINE (July 13, 2022), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2022/07/13/abortion-medications-set-to-become-next-legal-battlefield. Other FDA-approved drugs, such as methotrexate, also have off-label uses in medication abortions. *See, e.g.*, Malcolm Potts, *Non-Surgical Abortion: Who's For Methotrexate?*, 346 LANCET 655–56 (Sept. 1995).

[22] 21 U.S.C. § 393(b)(1).

[23] Misoprostol, indicated for reducing risk of certain ulcers, is frequently used for medication abortion, and bears a boxed warning that it can "CAUSE . . . ABORTION." *See Medical Information: Cytotec® (misoprostol) Boxed Warning*, PFIZER, https://www.pfizermedicalinformation.com/en-us/cytotec/boxed-warning (last visited Apr. 20, 2023); *see also* 21 C.F.R. § 201.57(c)(6)(i) (FDA may "require[]" a "specific warning relating to a use . . . if the drug is commonly prescribed for a disease or condition and such usage is associated with a clinically significant risk or hazard.").

[24] *See* Belluck, *supra* note 2 (discussing practical concerns in an uncertain legal framework); President Joseph Biden directed the Secretary of Health and Human Services (HHS), which oversees FDA, to "protect women's access to critical medications for reproductive health care that are approved by the Food and Drug Administration—including . . . medication abortion." Press Release, The White House, FACT SHEET: President Biden Announces Actions in Light of Today's Supreme Court Decision on Dobbs v. Jackson Women's Health Organization (June 24, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/24/fact-sheet-president-biden-announces-actions-in-light-of-todays-supreme-court-decision-on-dobbs-v-jackson-womens-health-organization/.

for intended uses.[25] Nonetheless, binding precedent on FDA preemption places substantial limitations on state powers to limit access to abortion-related drugs, especially where FDA has approved those drugs as safe and effective.

II. OBSTACLES AND CONTRADICTIONS: FEDERAL LAW PROHIBITS SPECIAL RULES FOR ACCESS TO DISFAVORED FDA-APPROVED DRUGS

States cannot exercise their powers "to regulate the administration of drugs by the health professions . . . in a way that is inconsistent with federal law."[26] Historically, "not many examples" of such preemption have been litigated "because state legislatures and regulators do not readily seek confrontation with federal authority."[27] The FDCA resolves conflict between a state's regulation of drug *administration* and federal guarantees of drug *availability*.[28] The FDCA empowers FDA to implement a scheme ensuring the availability of safe and effective drugs.[29] Accordingly, once FDA has approved a drug, state power to prohibit[30] the sale or use of that drug for FDA-approved indications narrows substantially.[31] As a result, state laws regulating prescription drugs usually focus on the conduct of healthcare providers[32] and create monitoring regimes that enforce criminal penalties for unlawful use or distribution of

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[25] For example, All. for Hippocratic Med. v. FDA, 78 F.4th 210 (5th Cir. 2023), *stayed pending app. sub nom.* Danco Lab'ys v. All. for Hippocratic Med., 143 S. Ct. 1075 (2023), found standing to collaterally attack FDA drug approval decisions when "providing emergency treatment forces the [plaintiff] Doctors to divert time and resources away from their ordinary patients, hampering their normal practice," *id.* at 232, a claim that any physician treating anyone with an adverse drug reaction could make. The same decision also preliminarily enjoined FDA actions based solely on the biased factual pleadings of the plaintiffs, while ignoring the extensive scientific evidence that FDA considered. *Id.* at 246–47.

[26] Zogenix, Inc. v. Patrick (*Zogenix II*), No. 14-11689-RWZ, 2014 U.S. Dist. LEXIS 92382, at *11 (D. Mass. July 8, 2014).

[27] Colacicco v. Apotex, Inc., 521 F.3d 253, 266 (3d Cir. 2008), *cert. granted, judgment vacated*, 556 U.S. 1101 (2009).

[28] FDA drug approval "is tantamount to a required license to sell the drug or device in the United States." Talley v. Danek Med., Inc., 179 F.3d 154, 160 (4th Cir. 1999). *See* Abney v. Amgen, Inc., 443 F.3d 540, 548–50 (6th Cir. 2006) (rejecting various state-law theories that purported to govern distribution of FDA-regulated investigational drug). *Cf.* Gonzales v. Oregon, 546 U.S. 243, 270 (2006) (distinguishing, in the controlled substances context, between federal power to limit physician "prescription-writing powers" and state power "to regulate the practice of medicine generally").

[29] *See* 21 U.S.C. § 393(b).

[30] Whether a state ban on the sale of a product that is legal and regulated at the federal level may independently violate the Commerce clause, see, e.g., Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris, 729 F.3d 937, 950 (9th Cir. 2013), is beyond the scope of this Article.

[31] *Zogenix II*, 2014 U.S. Dist. LEXIS 92382, at *10. For a comprehensive review of FDA regulation concerning off-label uses generally, see James M. Beck, *Off-Label Use in the Twenty-First Century: Most Myths and Misconceptions Mitigated*, 54 UIC J. MARSHALL L. REV. 1 (2021).

[32] Common state guidance may include mandates for continuing medical education, limits on the supply of medication provided with a single prescription, and an array of other regulations. *See* OPIOID RESPONSE NETWORK, OPIOID REGULATIONS: STATE BY STATE GUIDE (Jan. 2021), https://www.acep.org/globalassets/sites/acep/media/by-medical-focus/opioids/opioid-guide-state-by-state.pdf.

certain drugs.[33] But does federal preemption exist when state law creates obstacles to the availability of FDA-approved products?

The rationale for FDCA-based obstacle preemption of state law begins with *Buckman Co. v. Plaintiffs' Legal Committee*—a 2001 product liability decision involving medical devices.[34] *Buckman* prevents state courts from hearing suits on fraud theories challenging the veracity of manufacturers' regulated submissions to FDA (so-called "fraud-on-the-FDA") because those claims "inevitably conflict with FDA's responsibility to police fraud consistently with the agency's judgment and objectives."[35] The state tort claims impinged on FDA's mandate by allowing state-law juries to ignore FDA decisions as fraudulently induced, and therefore created an obstacle to FDA's regulatory scheme that was subject to implied FDA preemption.[36] *Buckman* invites judges to scrutinize second-order effects of state law that could interfere with FDA's guarantee of consistent access to safe and effective medicines as a matter of federal law.[37]

Buckman thus demonstrates that federal law can preempt even *implied* obstacles to FDA's regulatory mandate.[38] Courts considering FDA preemption must analyze a law's operation and effects to assess the impact of a medication-restricting law on FDA's mandate.[39] The line of decisions in *Zogenix, Inc. v. Patrick*, discussed in more detail below, consider state law and policies implicated in the regulation of disfavored drugs, applying a fact-intensive analysis to various attempts by the state to limit access to a novel opioid.[40] In a series of three opinions, the District Court of Massachusetts assessed the state regulation of an FDA-approved drug as a "last-resort opioid" because the opioid lacked an "abuse-deterrent formulation" that the state preferred.[41] Because FDA had considered the lack of an abuse-resistant formulation in its decision that the drug was safe and effective, federal law preempted state regulation to address the same issue.[42]

FDA's public health-based authority over prescription drug safety and effectiveness should preclude some measures that rely on *Dobbs'* emphasis on state interest in fetal life, especially given the breadth of state efforts to inhibit access to abortion-related drugs.[43] Another body of precedent, discussed in Part III, governs state-law attempts to prohibit the sale of FDA-approved products under the impossibility preemption

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[33] Corey S. Davis, Matthew Pierce & Nabarun Dasgupta, *Evolution and Convergence of State Laws Governing Controlled Substance Prescription Monitoring Programs, 1998–2011*, 104 AM. J. PUB. HEALTH 1389 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4103230/.

[34] Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001).

[35] *Id.* at 350.

[36] *Id.* at 348.

[37] *See id.* at 350–52 (summarizing second-order effects of fraud-on-the-FDA claims that interfere with FDA's regulatory mandate).

[38] *Id.* (holding that state law claims which "conflict with" federal law are "impliedly pre-empted by federal law").

[39] *See id.* at 348.

[40] Zogenix, Inc. v. Patrick (*Zogenix II*), No. 14-11689-RWZ, 2014 U.S. Dist. LEXIS 92382, at *13 (D. Mass. July 8, 2014).

[41] *Id.*

[42] *Id.* at *3, *15.

[43] *Id.* at *8–9

rubric. In its *Bartlett* decision, the Supreme Court has spoken more clearly to the effect that "an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether."[44] By contrast, *implied* preemption of state-created obstacles to federal powers may limit traditional state powers to regulate medicine within their borders.[45] Although states may act to protect public health, they may not do so in defiance of federal regulation to the same effect[46]: "Pre-emption is not a matter of semantics. A State may not evade the pre-emptive force of federal law by resorting to creative statutory interpretation or description at odds with the statute's intended operation and effect."[47] Thus, state laws that affect abortion-related drugs may be scrutinized by the courts for both textual and functional conflict with FDA's regulation of those same drugs.[48]

A. Buckman's Implied Obstacle Preemption: Keystone to FDA Preemption

Congress directed FDA to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products," a mandate that includes ensuring drugs are "safe and effective[.]"[49] *Buckman* tested the scope of FDA's regulatory mandate, as the Supreme Court considered the ability of private plaintiffs to sue based on issues FDA had resolved through its approval process.[50] *Buckman* has already produced two decades of precedent governing pharmaceutical product liability actions and the ongoing opioid crisis.[51] *Buckman* and its progeny will likely play a key role in shaping future litigation over the permissible scope of state restrictions on abortion-related medication.

In *Buckman*, plaintiffs filed suit against a medical device manufacturer for alleged problems with its FDA-cleared bone implants. The manufacturer submitted several applications to FDA that "sought § 510(k) approval for its . . . device."[52] The stated intended use in the original application was for the implant's employment in spinal surgeries.[53] FDA rejected that use for lack of "substantial equivalence to a predicate device."[54] FDA also rejected a second, supplemental application because the device "posed potential risks not exhibited by other spinal-fixation systems."[55] Finally, the manufacturer split its device application into two parts—one for a plate and one for a

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[44] Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 488 (2013).

[45] These "categories of preemption are not 'rigidly distinct.'" Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 373 n.6 (2000) (quoting English v. Gen. Elec. Co., 496 U.S. 72, 79 n.5 (1990)).

[46] *See* discussion *infra* Section II.C; *see also* Cohen et al., *supra* note 6, at 43–58 (describing conflicts between state regulation of abortion drugs and FDA regulation).

[47] Wos v. E. M. A., 568 U.S. 627, 636 (2013).

[48] *See* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001).

[49] 21 U.S.C. § 393.

[50] *Buckman Co.*, 531 U.S. at 341.

[51] *See* Beck, *supra* note 31, at 14–19.

[52] *Buckman Co.*, 531 U.S. at 346.

[53] *Id.*

[54] *Id.*

[55] *Id.*

screw—with intended uses in the arms and legs. The similarity of this new application to already approved devices caused FDA to provide market clearance for the implant.[56]

Numerous plaintiffs later claimed injury from the off-label implantation of the orthopedic bone screws in their spines—the use FDA originally found to be insufficiently supported.[57] These claims alleged that the long-bone intended use in the manufacturer's approved application deprived FDA of the opportunity to assess the risks and benefits of off-label spinal use.[58] Plaintiffs alleged that, but for defendant's "fraudulent representations to the FDA as to the intended use" of the device, FDA would not have approved it.[59] The Court decided that state-law fraud claims of this sort "conflict[ed] with, and are therefore impliedly pre-empted by federal law."[60]

The Supreme Court held that fraud claims attacking submissions to FDA presented an obstacle to FDA's regulatory scheme by "skew[ing]" the "delicate balance of statutory objectives" that FDA sought to pursue.[61] The seven-justice majority held, first, that preemption bars claims attacking agency decisions as fraudulently obtained, and second, that private persons lack the ability to enforce the FDCA and thus cannot assert claims in which purported FDCA violations are a "critical element."[62] The majority's analysis looked to: 1) FDA's extensive disclosure requirements; 2) FDA's ability to detect, deter, and punish fraud; 3) FDA's nuanced position on off-label use; and 4) that tort claims attacking the adequacy of submissions to FDA could gum up the regulatory works with additional, unnecessary, and undesired paper.[63] In particular, the FDCA "amply empowers the FDA to punish and deter fraud against the Agency."[64] Ultimately, the Court held that "State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives."[65] Thus, *Buckman* unanimously held them preempted.[66]

Following *Buckman*, a key question is how dramatically a state law may stretch the statutory goals of FDA before preemption bars the claim. In *Levine*, the majority in a drug warning case found no obstacle preemption because Congress "determined that widely available state rights of action provided appropriate relief for injured consumers."[67] In dissent, however, Justice Alito (who also wrote *Dobbs*) reiterated *Buckman*'s key holding that "[w]here the FDA determines, in accordance with its statutory mandate, that a drug is on balance 'safe,' our conflict pre-emption cases prohibit any State from countermanding that determination."[68] Litigation over state efforts to restrict the availability of FDA-approved drugs present a much more direct

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[56] *Id.*

[57] *Id.* (noting that plaintiffs filed "some 2,300 civil actions related to these medical devices").

[58] *Id.* at 346–47.

[59] *Id.* at 347.

[60] *Id.* at 348.

[61] *Id.*

[62] *Id.* at 353.

[63] *Id.* at 348–51.

[64] *Id.*

[65] *Id.*

[66] *Id.* at 353.

[67] Wyeth v. Levine, 555 U.S. 555, 574 (2009).

[68] *Id.* at 609 (citing *Buckman Co.*, 531 U.S. at 348) (dissenting opinion).

challenge to FDA authority than the private warning claim in *Levine*, and the sparse applicable law to date suggests a different outcome—which the next section addresses.

B. A Spectrum of Permissible State Action: Zogenix and Disfavored Drugs

In three opinions assessing a range of state-law restrictions, the *Zogenix* litigation[69] sheds light on how *Buckman*-based preemption applies to state-disfavored, but FDA-approved medications. The Commonwealth of Massachusetts' forced de-escalation of its restrictions on that disfavored drug, a novel opioid, provides examples of several types of permissible, prohibited, or questionably context-dependent state regulations. This line of cases demonstrates how courts may consider a spectrum of restrictions of varying severity, and the factors involved in applying federal preemption to implied or actual state-enacted obstacles to FDA's regulatory mandate.

In *Zogenix*, Massachusetts sought to combat the escalating opioid epidemic sweeping the United States, in part, by restricting the distribution of a prescription drug due to its safety-related disagreements with FDA. Plaintiff Zogenix received FDA approval to manufacture and distribute its new drug, "the only hydrocodone analgesic on the market whose sole active ingredient is hydrocodone," a composition of special benefit to some patients because "[o]ther analgesics contain acetaminophen, which can cause liver damage."[70] However, the new drug, unlike competing products, lacked an "abuse-resistant formulation" to prevent use via inhalation or injection.[71] Soon after the new drug's FDA approval, the governor of Massachusetts declared a public health emergency to combat "opioid addiction" and ordered the Massachusetts Public Health Commissioner to take steps to control the supply of opioids.[72]

That order led to *Zogenix I*, in which the court enjoined the essentially *carte blanche* discretion given to a state executive branch official to prohibit an FDA-approved drug. Exercise of that authority explicitly banned plaintiff's FDA-approved drug by requiring the state Department of Public Health to "immediately *prohibit* the prescribing and dispensing of [the drug] until [the Department of Public Health] determined that adequate measures to safeguard against diversion, overdose, and misuse had been implemented."[73] As discussed herein, state reliance on risks of drug "diversion" and "misuse" should prove relevant to future state justifications of restrictions on abortion-related drugs.[74] Notwithstanding these justifications, *Zogenix I* held that "[i]f the Commonwealth were able to countermand the FDA's determinations and substitute its own requirements, it would undermine the FDA's ability to make drugs available to promote and protect the public health."[75] This ruling accords with the seemingly elementary principle that a state may not ban FDA-

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[69] *See generally* Zogenix, Inc. v. Patrick (*Zogenix II*), No. 14-11689-RWZ, 2014 U.S. Dist. LEXIS 92382 (D. Mass. July 8, 2014).

[70] Zogenix, Inc. v. Patrick (Zogenix I), No. 14-11689-RWZ, 2014 U.S. Dist. LEXIS 51840, at *2 (D. Mass. Apr. 15, 2014).

[71] *Id.*

[72] *Id.* at *2–3.

[73] *Id.* (emphasis added).

[74] *See* discussion *infra* Section II.C.

[75] *Zogenix I*, 2014 U.S. Dist. LEXIS 51840 at *4–5.

approved drugs as "inherently dangerous even when taken as directed and when appropriately stored."[76]

In *Zogenix II*, the district court considered whether to enjoin a less stringent restriction, enacted in response to *Zogenix I*, which: 1) demanded a preliminary showing that other medications had failed before prescribing the disfavored drug, and 2) mandated certain pharmacy business practices that in practice rendered dispensing that drug impractical.[77] Following its loss in *Zogenix I*, Massachusetts enacted "regulations limiting the prescribing and handling of" the drug that amounted to "a *de facto* ban."[78] The regulatory restrictions at issue in *Zogenix II* required:

- Assessment of specified clinical data on an individual patient basis;
- An informed consent discussion with the patient of specific risk/benefit topics;
- The patient signing a contract specifying how the drug would be stored and used;
- Receipt of a letter of medical necessity which "verifies that other pain management treatments have failed;"
- Documentation in the patient's medical record; and
- Technical licensure requirements, including that a "certified pharmacy technician, pharmacy technician, pharmacy technician trainee, or pharmacy intern may not handle" the drug.[79]

Ultimately, *Zogenix II* had to consider the plaintiff's challenges to only two provisions: the letter of medical necessity and the pharmacist handling restriction.[80] Either of these regulations effectively "banned [the drug's] prescribing, ordering, dispensing or administration" by interfering with FDA's previous balance of competing safety and availability factors.[81] *Zogenix II* concluded that, while states do have the power "to regulate the administration of drugs by the health professions," no state may "exercise those powers in a way that is inconsistent with federal law."[82] Massachusetts has power to regulate administration of controlled substances (which abortion-related drugs are not), but could not exercise that power to prohibit use of an FDA-approved drug through the chilling effect of a vague, uncertain, and onerous regulatory scheme.[83] As for the mandatory "letter of medical necessity," *Zogenix II* held that relegating the plaintiff's drug to "last-resort" status had "undeniably" made the drug less available.[84] Further, due to the incompatibility of the pharmacist-only

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[76] Mayor of Baltimore v. GlaxoSmithKline, LLC, No. 24-C:20-004788, 2022 Md. Cir. Ct. LEXIS 1, at *12 (Md. Cir. Jan. 28, 2022).

[77] Zogenix, Inc. v. Patrick (*Zogenix II*), No. 14-11689-RWZ, 2014 U.S. Dist. LEXIS 92382, at *3–4 (D. Mass. July 8, 2014).

[78] *Id.* at *2, *6.

[79] *Id.* at *4.

[80] *Id.* at *7.

[81] *Id.* at *3.

[82] *Id.* at *11.

[83] *Id.* at *16.

[84] *Id.* at *13.

prescription fulfillment requirement with pharmacy business practices, this aspect of the state's scheme also appeared to pose a significant obstacle to the drug's distribution.[85] Both of these provisions thus presented "a constitutional problem," given the drug's FDA approval.[86] On the basis of these "tentative" conclusions, *Zogenix II*: 1) issued a preliminary injunction against the letter of medical necessity, pending modification of the problematic language; and 2) denied the motion to enjoin the "pharmacist-only" regulation without prejudice, pending "a more detailed submission" on whether pharmacies subject to that personnel restriction could carry the new drug.[87]

Finally, the state backtracked still more, removing the provision held to be preempted in *Zogenix II* and deleting the "last resort" restriction on prescriptions.[88] Those modifications led to *Zogenix III*, which vacated the preliminary injunction entered in *Zogenix II*. The state was permitted to retain a letter of medical necessity requirement once it "omit[ted] the conflicting, troublesome language" that amounted to a ban by other means.[89] The revised contents of the required letter now "mimic[ked] the language [of] the Food and Drug Administration approv[al] for [the drug's] label."[90] *Zogenix III* reiterated that the requirement that "other pain management treatments have 'failed'" was both too vague to provide meaningful guidance and deprived doctors of the ability to use a first-line treatment found safe and effective by FDA.[91] The new regulations without that phrase "no longer offend[ed] the Supremacy Clause of the United States Constitution . . . . The obstacle—mandatory preliminary prescribing of other [drugs]—has now been removed."[92] Without a requirement to try other drugs first, and with the drug readily available in pharmacies, the state no longer imposed an obstacle to pharmaceutical distribution that conflicted with the federal statutory scheme created by FDA.[93]

Zogenix II is the most revealing of this trio of opinions, as that decision critically assessed a range of state enactments intended to restrict the availability of an FDA-approved medication, and determined, in the context of a preliminary objection, that the two most generalized restrictions likely intruded too deeply into FDA's approval power (potentially interfering with medical judgment and pharmacy operations). Although the plaintiff did not develop the factual record necessary to support a challenge to the state's "pharmacist-only" regulation, there remains the possibility that a properly supported challenge could succeed in showing another preempted obstacle—"sufficient detail that pharmacies will not carry" an FDA-approved drug, given a state's regulation.[94] Courts making similar evaluations of possibly preempted

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[85] *Id.* at *14–15.

[86] *Id.*

[87] *Id.* at *16.

[88] Zogenix, Inc. v. Patrick (*Zogenix III*), No. 14-11689-RWZ, 2014 U.S. Dist. LEXIS 120866, at *7–8, (D. Mass. Aug. 8, 2014).

[89] *Id.* at *7.

[90] *Id.* at *8.

[91] *Id.* at *7–8.

[92] *Id.* at *3, *8.

[93] *Id.* at *8.

[94] *See* Zogenix, Inc. v. Patrick (*Zogenix II*), No. 14-11689-RWZ, 2014 U.S. Dist. LEXIS 92382, at *16 (D. Mass. July 8, 2014).

state restrictions, could, as in *Zogenix*, permit restrictions mandating patient-specific considerations, like assessments, discussion (as long as it "mimics" FDA-approved labeling), or even continuing contractual arrangements; facility recordkeeping or storage requirements would presumably be acceptable. Such tactics resemble certain pre-*Dobbs* state measures to limit abortion access.[95] However, restrictions that limit all patients' access to FDA-approved drugs raise constitutional problems, including interfering with the ability of medical professionals to exercise prescribing judgment, and others identified in the course of the *Zogenix* litigation. The *Zogenix* court accurately stated that it "should not find preemption where there is no clearly discernible conflict between state and federal law[]," while conversely holding that state governments "may not use vague regulations to sidestep or countermand federal law."[96] As discussed in *Zogenix*, vague state-law regulations having the effect of interrupting patient and physician access to drugs that FDA has approved as safe and effective should be preempted by the FDCA.

More broadly, the *Zogenix* cases demonstrate that states can be expected to target pharmacies, due to the preemptive effect of FDA regulation of drug manufacturers themselves. Rather than direct assaults on the FDCA regulatory scheme, restrictions on pharmacy—and perhaps wholesaler[97]—practices will become more common. *Zogenix* also clarifies that, while states possess formidable regulatory power over healthcare providers, that power cannot override, in fact or in effect, FDA's determination, essential to FDA's approval of a product, that a drug's benefits outweigh its risks in general. The state cannot force medical providers within its borders to interpose a "no" where FDA, exercising federal power, has said "yes."[98] The court further stated that, "[T]o the extent that Congress intended for the FDA to make definitive and nationally uniform judgments about the safety and effectiveness of pharmaceutical products, state efforts to second-guess the agency's determinations certainly would threaten to frustrate those somewhat different purposes."[99]

In *Zogenix*, state restrictions contradicting FDA approval likely presented a preempted obstacle, but the state backed down rather than risk a definitive judicial

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[95] *See generally* Sybil Shainwald, *Reproductive Injustice in the New Millennium*, 20 WM. & MARY J. WOMEN & L. 123, 124 (2013) ("State restrictions can be broken down into four general areas: (1) mandating unnecessary medical procedures, such as ultrasounds; (2) increased level of scrutiny on abortion providers (e.g., requiring abortion providers to have facilities with technology as advanced as hospitals); (3) requirements for abortion providers to have admitting privileges at hospitals; and (4) time limits, such as . . . bans on abortions performed after twenty weeks."). *See also* Katherine Kubak, Shelby Martin, Natasha Mighell, Madison Winey & Rachel Wofford, *Abortion*, 20 GEO. J. GENDER & L. 265, 269–70 (2019) (discussing common pre-*Dobbs* state regulations on abortion that passed the "undue burden" test established by *Planned Parenthood v. Casey*, 505 U.S. 833 (1992); restrictions included waiting periods, informed consent requirements, and parental notification laws).

[96] *Zogenix II*, 2014 U.S. Dist. LEXIS 92382, at *15–16.

[97] Express preemption under the Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587 (2013), 21 U.S.C. § 360eee-4I, will constrain state authority over wholesaling of FDA-approved drugs; however, the FDA regulations that would effectuate such preemption are not yet final. *See* X-Gen Pharms., Inc. v. Dep't of Fin. & Pro. Regul., 2022 Ill. App. (4th) 210325, 2022 Ill. App. LEXIS 497, at *P15–17 (Ill. App. Nov. 23, 2022) (discussing PMA preemption and status of drug wholesaler regulations).

[98] "[N]ormally Congress would not want States to forbid, or to impair significantly, the exercise of a power that Congress explicitly granted." Barnett Bank, N.A. v. Nelson, 517 U.S. 25, 33 (1996) (state law forbidding bank from selling insurance that federal law permitted held preempted).

[99] Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 MICH. ST. L. REV. 1, 12 (2016) (footnotes omitted).

determination to that effect. In deciding whether the state had gone too far, however, *Zogenix II* clarified that "[w]hat is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects."[100] By that standard, the state intruded on FDA's mandate by "trying to make scarce or altogether unavailable a drug that FDA, by approving it, has said should be available."[101]

The tertiary restrictions in *Zogenix*, which received little attention, are also important indicators of the scope of permissible state regulations targeting disfavored medicines. These permissible regulations included requirements for storage, packaging, counseling, patient warnings, and even surveillance of patients via prescription drug monitoring programs.[102] Notably, the court permitted Massachusetts to mandate that providers submit a letter of medical necessity in order for their patients to access a drug—but only after the letter's requirements were modified to avoid interference with medical judgment and to parallel FDA's approval conditions. In the abortion context, regulations similar to those upheld in *Zogenix* are apt to pass judicial muster, at least as to FDCA-preemption challenges.

Future courts following preemption models consistent with *Zogenix* will likely decide that effective frustration of access to FDA-approved drugs poses "significant constitutional concerns" that conflict with FDA authority to approve products for nationwide marketing.[103]

C. Application to State Regulation of Medication Abortion

States with post-*Dobbs* restrictive abortion policies have also been restricting the availability of abortion-related drugs.[104] Some states have gone further by passing specific restrictions on abortion-related medications.[105] With these restrictions, the states are exploring various options with the same goal—to reduce the number of elective abortions.[106] Efforts by reproductive health groups to distribute such medications in states that limit abortion access[107] are likely to confront increasingly

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[100] *Zogenix II*, 2014 U.S. Dist. LEXIS 92382, at *8 (quoting Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 373 (2000)).

[101] *Id.* at *9.

[102] *Id.* at *4 (listing measures imposed by the Massachusetts Board of Registration in Medicine, including those upheld following *Zogenix III*).

[103] *Id.* at *14.

[104] *See, e.g.*, John Hanna, *More Turn to Abortion Pills by Mail, with Legality Uncertain*, AP NEWS (Nov. 13, 2021), https://apnews.com/article/coronavirus-pandemic-abortion-texas-covid-19-pandemic-health-13c2fbe3f1de416d88a5ef6d1ca3406e.

[105] *See, e.g.*, KY. REV. STAT. ANN. §§ 311.710 to 311.820.

[106] The Kaiser Family Foundation tracks state abortion restrictions along four measures: 1) provision by a physician, 2) complete or partial ban on medication abortions, 3) telemedicine and/or physical presence requirements, and 4) provision of medication abortion by an advanced practice clinician. Many such laws are enjoined or otherwise not in effect, but all have the effect of reducing access to abortion-related medications, and state laws reflect an explicit intent to minimize the number of abortions through regulation. *See State Requirements for the Provision of Medication Abortion*, KAISER FAM. FOUND. (Nov. 2022), https://www.kff.org/womens-health-policy/state-indicator/state-requirements-for-the-provision-of-medication-abortion); *see also The Availability and Use of Medication Abortion*, KAISER FAM. FOUND. (Feb. 24, 2023), https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/.

[107] *See* Belluck, *supra* note 2.

stringent state resistance.[108] In any state, however, FDCA preemption limits state restrictions on access to abortion-related medication that interfere with FDA's mandate to ensure public access to safe and effective medicines.[109]

Federal and state officials have already clashed over access to medication abortion, with litigation in progress. Attorney General Merrick Garland warned, when *Dobbs* was decided:

> [T]oday's decision does not eliminate the ability of states to keep abortion legal within their borders. And the Constitution continues to restrict states' authority to ban reproductive services provided outside their borders. . . . States may not ban Mifepristone based on disagreement with the FDA's expert judgment about its safety and efficacy.[110]

Similarly, the Secretary of HHS declared that his department "will continue to support the FDA and its rigorous scientific review for these safe and effective drugs," including mifepristone.[111] A Biden Administration "Reproductive Rights Task Force" is working with private reproductive rights advocates to address the current array of restrictions on access to abortion-related drugs.[112] Access to reproductive healthcare after *Dobbs* benefits from 2021 FDA guidance that permanently lifted an in-person prescription requirement for mifepristone. FDA "conducted a comprehensive review of the published literature, relevant safety and adverse event data, and information provided by" the public.[113] These and other efforts have impacted state law that seeks to impede continuing access to abortion care, but so far FDCA preemption has yet to play a substantial role.

FDA continues to impose product-specific controls on access to medication abortions through Risk Evaluation and Mitigation Strategy (REMS) requirements.[114] REMS assessments consider six statutory factors to decide when special safeguards should accompany drug approval.[115] The REMS for FDA approval of mifepristone and

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[108] *See, e.g.*, 201 KY. ADMIN. REGS. 2:030 (2022) (requiring pharmacists in other states to obtain a "Non-Resident Pharmacist License" to "practice pharmacy to citizens in Kentucky").

[109] *See* Pharm. Rsch. & Mfrs. of Am. v. District of Columbia, 406 F. Supp. 2d 56, 60 (D.D.C. 2005) (state law creating a private right for any "affected party" to sue for excessive drug prices preempted due to conflict with the purpose and execution of federal patent laws governing drugs).

[110] Press Release, U.S. Dep't of Just., Attorney General Merrick B. Garland Statement on Supreme Court Ruling in Dobbs v. Jackson 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.

[111] Press Release, U.S. Dep't of Health & Hum. Servs., Remarks by Secretary Xavier Becerra at the Press Conference in Response to President Biden's Directive following Overturning of Roe v. Wade (June 28, 2022), https://www.hhs.gov/about/news/2022/06/28/remarks-by-secretary-xavier-becerra-at-the-press-conference-in-response-to-president-bidens-directive-following-overturning-of-roe-v-wade.html.

[112] Press Release, The White House, FACT SHEET: President Biden Issues Executive Order at the First Meeting of the Task Force on Reproductive Healthcare Access (Aug. 3, 2022), https://www.whitehouse.gov/briefing-room/statements-ssreleases/2022/08/03/fact-sheet-president-biden-issues-executive-order-at-the-first-meeting-of-the-task-force-on-reproductive-healthcare-access-2/.

[113] Pam Belluck, *F.D.A. Will Permanently Allow Abortion Pills by Mail*, N.Y. TIMES (Dec. 16, 2021), https://www.nytimes.com/2021/12/16/health/abortion-pills-fda.html.

[114] 21 U.S.C. § 355-1(a)(1).

[115] *Id.* (FDA considers "(A) The estimated size of the population likely to use the drug involved. (B) The seriousness of the disease or condition that is to be treated with the drug. (C) The expected benefit of the drug with respect to such disease or condition. (D) The expected or actual duration of treatment with the

Mifeprex requires that: 1) patients sign an acknowledgement that their provider provided certain drug-related information, and 2) a certified provider fills the prescription.[116] A mifepristone manufacturer asserted that, under *Buckman*, states cannot usurp FDA's REMS authority to impose further restrictions on drug availability for reasons already addressed through the REMS (or FDA approval more broadly).[117] That argument would preclude states from regulating access to abortion-related drugs based on the number of "likely" drug users, the seriousness of underlying conditions, or a risk/benefits analysis.[118] The REMS, as a final agency action of FDA, constitutes binding federal law that preempts state law.[119]

The recent decision in *Sorsaia*[120] provides insight into how novel state abortion restrictions may, or may not, conflict with a REMS applicable to an abortion-related drug. The mifepristone manufacturer–plaintiff sued several West Virginia defendants to enjoin enforcement of state law that made abortion "illegal in the State, subject to a limited series of exceptions."[121] Applying a presumption against preemption, *Sorsaia* interpreted FDA's statutory mandate to impose REMS[122] narrowly, to apply only to "FDA's *own restrictions* on a drug," and not as "a command that the FDA assure access for all patients."[123] Congressional intent, when this amendment was enacted, could not have extended to protecting access to abortion generally, because "no Congressperson in 2007 could have credibly doubted that abortion was legal."[124]

However, state restrictions that directly conflicted with the relevant mifepristone REMS were preempted: "There is one provision which is unambiguously preempted by the [current] REMS: the prior restriction on prescribing mifepristone via telemedicine. . . . The [current] REMS reflects a determination by the FDA that when

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drug. (E) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug. (F) Whether the drug is a new molecular entity"). FDA also "may require that the [REMS] for a drug include such elements as are necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness." *Id.* at (f)(1). Such elements, however, shall "not be unduly burdensome on patient access to the drug." *Id.* at (f)(2)(C).

[116] *Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. FOOD & DRUG ADMIN. (Mar. 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[117] Compl., *GenBioPro, Inc.* (S.D. Miss. Oct. 9, 2020) (No. 3:20-cv-00652), ECF No. 1. Similar actions have recently been filed that challenge mifepristone restrictions North Carolina and West Virginia. *See* Bryant v. Stein, No. 1:23-cv-00077 (M.D.N.C., filed Jan. 25, 2023), and GenBioPro, Inc. v. Sorsaia, No. 3:23-cv-00058 (S.D.W. Va., filed Jan. 25, 2023).

[118] 21 U.S.C. § 355-1(a)(1).

[119] *See* Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1679 (2019) (preemptive effect of FDA actions limited to agency actions "taken pursuant to the Food and Drug Administration's (FDA's) congressionally delegated authority" and "carrying the force of law"); *see also* U.S. FOOD & DRUG ADMIN., REMS: FDA'S APPLICATION OF STATUTORY FACTORS IN DETERMINING WHEN A REMS IS NECESSARY—GUIDANCE FOR INDUSTRY (Apr. 2019), https://www.fda.gov/media/100307/download.

[120] GenBioPro, Inc. v. Sorsaia, No. CV 3:23-0058, 2023 WL 5490179 (S.D.W. Va. Aug. 24, 2023) (*Sorsaia*).

[121] *Id.* at *1 (footnote omitted).

[122] 21 U.S.C. § 355-1(f).

[123] 2023 WL 5490179, at *6 (emphasis in original).

[124] *Id.* at *7.

mifepristone is prescribed, it may be prescribed via telemedicine."[125] Unlike the state restrictions on physicians, the telemedicine provision was not "upstream" of FDA regulation.[126] Instead, it "dictate[d] the manner in which mifepristone may be prescribed," which was "a determination which Congress has allocated to the FDA."[127] The conflict between state law and the mifepristone REMS created "impossibility preemption" because a prescribing physician "could not comply with both the access determination made by the FDA and the access determination made by [the state] as to telehealth."[128]

Under a similar rationale, where FDA considers the risk of unlawful drug diversion under its regulatory mandate, a state ban of an abortion-related off-label use based on similar considerations cannot interfere with that drug's availability for on-label purposes, such as treating miscarriages.[129]

Realistically, however, it is hazardous to draw sweeping conclusions at this early date about how courts will handle the interaction of FDA preemption precedent with *Dobbs*. For one thing, opponents of medication abortion understand the power of FDCA-based preemption. Thus, after *Dobbs*, every aspect of FDA's regulation of mifepristone has been under attack, from its original approval to FDA's post-*Dobbs* modifications to the product's REMS.[130] The scope of preemption will, of course, turn on the administrative validity of FDA's regulatory activity.

It is possible to identify certain trends in state law, proceeding along a rough spectrum from narrow, medication-specific regulation, to broad laws that ban abortion even beyond a state's borders. Depending on text, context, and implementation, laws restricting abortion-related medication may interfere with access to an FDA-approved drug with multiple indications that include abortion. The analysis herein does not dwell on the distinctions among various sorts of state action—statutory, regulatory or

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[125] *Id.* at *10 (citations and footnote omitted).

[126] *Id.* at *11.

[127] *Id.* (citing 21 U.S.C. § 355-1(f)(3)(C) (REMS may specify that a "drug be dispensed to patients only in certain health care settings")).

[128] *Id. Sorsaia* also noted that certain "other prior restrictions"—involving a waiting period and various counseling requirements—might be similarly preempted, since "they similarly dictate the way mifepristone may be prescribed," but since those restrictions were not in effect, the court did not issue a ruling. *Id.* (discussing W. Va. Code § 16-2I-2).

[129] *See* Zogenix, Inc. v. Patrick (*Zogenix I*), No. 14-11689-RWZ, 2014 U.S. Dist. LEXIS 51840, at *3 (D. Mass. Apr. 15, 2014) (striking down a law premised on withholding access to a drug until a state agency determined "that adequate measures to safeguard against diversion, overdose, and misuse had been implemented"). Analogously, in *United States v. Locke*, 529 U.S. 89, 108–17 (2000), state-law regulations concerning oil tankers were preempted because supreme federal regulation governed the same issues: "design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning," but imposed different requirements. *Id.* at 101. Preemption barred a state from "attempt[ing] to go farther than Congress has seen fit to go." *Id.* at 115 (citation and quotation marks omitted). Congress, not individual states, had to decide "whether their regulatory scheme, which demands a high degree of uniformity, is adequate." *Id.* at 117.

[130] *See* All. for Hippocratic Med. v. FDA, ___ F. Supp.3d ___, No. 2:22-CV-223-Z, 2023 WL 2825871 (N.D. Tex. Apr. 7, 2023) (enjoining all of FDA's mifepristone actions, beginning with its 2000 initial approval, as administratively invalid for various reasons), *aff'd in part, vacated in part*, 78 F.4th 210 (5th Cir. 2023) (reinstating FDA drug approvals, but enjoining REMS and 2021 FDA guidance as administratively invalid), *stayed sub nom*. Danco Lab'ys v. All. for Hippocratic Med., 143 S. Ct. 1075 (2023) (all injunctions stayed pending appeal).

through medical licensing boards and similar regulatory bodies—only on the effect of state law on federal drug regulation under FDA's regulatory mandate.

Regulation of Drug Distribution: Laws that broadly restrict provision of "abortion-inducing" drugs to all women, because that drug may also be used to induce abortions, likely create functional obstacles to access to safe and effective medication, thereby contradicting what FDA regulations provide.[131] The strongest preemption case is where a state prohibits sale of a medication for one of its FDA-approved indications, but even in this situation, *Dobbs*' fetal-protective state interest creates uncertainty.[132] Nevertheless, FDA's regulatory mandate is sweeping, which should preclude states from contradicting FDA expertise through their own laws, barring congressional amendment of the FDCA itself to alter the existing balance. FDA's directive to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products" and ensuring that drugs are "safe and effective"[133] accounts for the risks to the lives of expectant mothers, fetal health, and diversion for unlawful purposes.[134] The REMS specific to abortion-related drugs (specifically mifepristone and Mifeprex) address these risks with medication-specific safeguards.[135] A state law that regulates the drug's availability that contradicts FDA's resolution of these issues inherently contradicts FDA's power to assure uniformity of drug availability throughout the nationwide drug market, creating an obstacle to FDA's purpose for the same reason.[136] As *Zogenix* demonstrates, state efforts to create an "abortifacient of last resort" (by regulating drug administration in a manner that restricts legal access to something less than what FDA permits) will be especially vulnerable to preemption.[137]

Outright Criminalization of Medication Abortion: Criminal penalties for distribution of abortion-related drugs to pregnant women also inherently conflict with FDA approval of such drugs as safe and effective for that use.[138] For most abortion-

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[131] *See, e.g.*, LA. REV. STAT. ANN. § 14:87.9 ("Criminal abortion by means of an abortion-inducing drug is committed when a person knowingly causes an abortion to occur by means of delivering, dispensing, distributing, or providing a pregnant woman with an abortion-inducing drug.").

[132] *See supra* notes 69–78 and accompanying text.

[133] 21 U.S.C. § 393.

[134] *Id.* § 355-1(a)(1) directs FDA to consider the overall patient "population," the drug's "expected benefit" for each intended use, the "seriousness of known or potential adverse events," and their "background incidence" in the population "likely to use" the drug.

[135] CTR. FOR DRUG EVALUATION & RSCH., U.S. FOOD & DRUG ADMIN., NDA 020687 MIFEPREX (MIFEPRISTONE) TABLETS, 200 MG, ANTIPROGESTATIONAL SYNTHETIC STEROID: RISK EVALUATION AND MITIGATION STRATEGY (REMS) (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_REMS_full.pdf [hereinafter FDA, MIFEPREX REMS].

[136] Thus, state restrictions on use of mifepristone and Mifiprex "will need to be reviewed one-by-one to determine whether they contradict" this FDA-imposed REMS. Grossi & O'Connor, *supra* note 6, at 48.

[137] *Cf.*, LA. REV. STAT. ANN. § 14:87.1(2) (2022) (excluding methotrexate from the definition of "Abortion-inducing drug" when it is used to treat ectopic pregnancy, but not providing a similar exemption for mifepristone, which is FDA-approved for the same indication).

[138] *E.g.*, TENN. CODE ANN. § 39-15-213 (prohibiting abortion via use of any instrument, medicine, drug, substance, or device to terminate pregnancy; violation punishable as a Class C felony, with exceptions to prevent death or serious injury of the unborn child or mother); *see also* Claire Galofaro, *Lawyer's Mission: Translate Tenn.'s Bewildering Abortion Ban*, AP NEWS (Sept. 5, 2022), https://apnews.com/article/abortion-health-knoxville-statutes-government-and-politics-1a92f84003556cdd071f6297cd5f43c0.

related drugs, FDA has approved indications for elective abortions in addition to other purposes that are likely to remain lawful in all states post-*Dobbs* (e.g., to aid treatment of miscarriage, ectopic pregnancy, or certain rheumatoid or autoimmune conditions). Several states criminalize use of abortion pills based on the progression of a pregnancy, and those penalties may apply to providers who treat serious medical risks with abortion-related medication, even in the context of a non-viable pregnancy.[139] Preemption may limit these state laws to the extent they chill legitimate medical judgment by not giving providers clear notice of what conduct they criminalize in the course of prescribing an FDA-approved medication for an approved indication.

General Abortion Bans or Restrictions: State abortion bans or restrictions often do not address medication abortions separately, but their vague language may encompass FDA-approved drug indications. State laws imposing generalized abortion prohibitions therefore must not impinge on drug availability for federally approved uses.[140] The first two states to pass restrictive abortion laws post-*Dobbs*, Indiana and West Virginia, provide instructive examples.[141] Generally, these laws bar abortion at all stages of pregnancy, with narrow exceptions for medical emergency and rape or incest reported to law enforcement.[142] Depending on state interpretation of what constitutes a "medical emergency," such restrictions may chill access to medications like Mifeprex and mifepristone by preventing physicians from prescribing them until a patient is *in extremis*, contrary to FDA's final actions guaranteeing access to those drugs. This could be viewed as an implied obstacle to FDA-approved indications and REMS conditions.

Private Enforcement Provisions: State laws creating a private bounty system have effects on FDA drug approval that resemble the sort of tort claims held to be preempted in *Buckman*.[143] They create unnecessary uncertainty and paperwork impeding medical providers' ability to prescribe FDA-approved drugs for FDA-approved indications because "ability to comply with state law depended on uncertain . . . third-party

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[139] TEX. HEALTH & SAFETY CODE ANN. § 171.063 (criminalizing prescription of abortion-related medication after seven weeks of pregnancy and preventing prescription via telehealth services); S.D. CODIFIED LAWS § 36-4-47 (criminalizing medication abortion via telemedicine); *cf.* S.B. 1, 122nd Gen. Assemb., Spec. Sess. (Ind. 2022), http://iga.in.gov/legislative/2022ss1/bills/senate/1) (codified in scattered sections of the Indiana Code including IND. CODE § 16-18-2-14) (criminalizing prescription of abortion-related medication after ten weeks of pregnancy, except for accidental or unintentional terminations of pregnancy).

[140] A state's general ban on abortion procedures, targeting physicians, may well be too far removed from drug prescription to conflict with FDA drug regulation. *See* GenBioPro, Inc. v. Sorsaia, No. CV 3:23-0058, 2023 WL 5490179, at *8 (S.D.W. Va. Aug. 24, 2023) (*Sorsaia*).

[141] Many states had passed "trigger laws" prior to the issuance of *Dobbs* with the effect of banning abortion immediately after it was issued, but these two states were the first to pass new bills following *Dobbs*, so their legislation better reflects state legislative consideration of the extent of state power under *Dobbs*. S.B. 1, 122nd Gen. Assemb., Spec. Sess. (Ind. 2022), http://iga.in.gov/legislative/2022ss1/bills/senate/1 (codified in scattered sections of the Indiana Code including IND. CODE § 16-18-2-14); H.B. 302, 2022 Leg., 3d Spec. Sess. (W. Va. 2022), http://www.wvlegislature.gov/Bill_Text_HTML/2022_SESSIONS/3X/bills/HB302%20ENG.pdf) (codified in scattered sections of the West Virginia Code including W. VA. CODE § 9-2-11).

[142] *E.g.*, W. VA. CODE § 16-2R-3.

[143] *See* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 353 (2001); *see also* S.B. 8, 87th Leg., Reg. Sess. (Tex. 2021) (permitting citizens to file suit against anyone who knowingly aids or abets an abortion).

decisions."[144] Allowing unconstrained individual citizen suits against persons authorized to prescribe drugs for abortion-related medication despite its FDA-approved indication potentially creates litigation-driven "skew[ing]" of "[t]he balance sought by the [FDA]" in a much more direct way than the *Buckman* claims, since they attacked only permissible *off-label use* of FDA-approved drugs.[145] A fortiori, *Buckman* should prohibit individual state-law claims that would impose liability for prescribing drugs for uses explicitly considered and approved by FDA.[146] Such litigation—assuming it actually occurs—would constitute a direct challenge to FDA's drug approval authority and inherently conflict with in-force agency approval decisions in the same way that allowing private plaintiffs to ignore allegedly "fraudulently" induced FDA decisions did in *Buckman*.[147] Thus, state-created causes of action that harass providers issuing legitimate prescriptions for FDA-approved drug uses interferes with FDA's guarantee of availability.

Extra-Territorial Laws: Some states have already proposed legislation broad enough to extend to the policing of extraterritorial behavior.[148] State efforts to interfere with interstate commerce in order to deter their citizens' ability to access FDA-approved abortion-related medications tread on fraught constitutional ground,[149] in addition to challenging FDA authority. *Buckman*, however, provides an alternative path to unconstitutionality. For example, registration regulations targeting out-of-state healthcare providers in order to obtain personal jurisdiction,[150] if used to pursue telemedicine prescriptions of abortion-related drugs, create the same state-law impediments to the availability of FDA-approved drugs for FDA-approved indications discussed above,[151] only with the effect of restricting drug availability nationwide. Similarly, this type of extraterritorial restriction raises preemption issues similar to *Zogenix*, to the extent that uncertainty created by novel restrictions inhibits prescriptions for FDA-approved indications (the uncertainty of who is a domiciliary of any given state creates an obstacle to the interstate prescription of drugs generally).[152] A proliferation of state-specific prescribing restrictions would be

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[144] PLIVA, Inc. v. Mensing, 564 U.S. 604, 623 (2011) (plurality opinion).

[145] *Buckman Co.*, 531 U.S. at 348.

[146] *Id.* at 350–51.

[147] *See supra* notes 32–37 and accompanying text.

[148] One example is Kentucky's recently proposed amendments to 201 KAR 2:030 that would require pharmacists anywhere in the country to apply for a "Non-Resident Pharmacist License" in order to "practice pharmacy to citizens in Kentucky." The intent of these amendments is to create personal jurisdiction over any pharmacist, anywhere, who prescribes drugs to Kentucky residents. Roxanne Hilton, Nicholas Meza & Brenda Maloney Shafer, *Kentucky Proposes First-in-Nation Non-Resident Pharmacist License—What's Next?*, JDSUPRA (Sept. 9, 2022), https://www.jdsupra.com/legalnews/kentucky-proposes-first-in-nation-non-6321609/.

[149] Interstate commerce-related and federalism-related constitutional issues that extraterritorial legislation creates are beyond the scope of this Article.

[150] Whether personal jurisdiction may be obtained over conduct unrelated to the state of registration via compliance with mandatory registration requirements is currently before the Supreme Court in *Mallory v. Norfolk Southern Railway Co.*, No. 21-1168 (U.S., filed Feb. 18, 2022).

[151] *See supra* notes 104–09, 141–45.

[152] Current HHS initiatives seek to expand, rather than restrict, remote access to healthcare services, including abortion. *See* Press Release, U.S. Dep't of Health & Hum. Servs., HHS Takes Action to Strengthen Access to Reproductive Health Care, Including Abortion Care (Aug. 26, 2022), https://www.

anathema to the nationwide market for prescription drugs that the FDCA has created and fostered for decades.

A state's enumerated purposes and other legislative history surrounding extraterritorial drug prescription restrictions, while not dispositive, may provide clear textual evidence justifying *Buckman*-based preemption. For example, Kentucky's proposed omnibus abortion restriction bill (including medication restrictions) contains forty recitals, including a summary of FDA's own findings on mifepristone and Mifeprex, as well as a justification to protect "the health and welfare of every woman considering a drug-induced abortion[.]"[153] Of course, these are permissible state-law goals, but their pursuit cannot countermand or frustrate FDA drug approvals.

As the *Zogenix* litigation demonstrates, many state-law requirements imposed on the prescription of FDA-approved drugs, including abortion-related medications, are not severe enough to rise to a preemptive level. Public health and welfare are areas of traditional state power that are particularly resistant to preemption.[154] These provisions are similar to the ones upheld in *Zogenix*, including regulation of the informed consent process, documentation of medical need, storage requirements, recordkeeping, "cooling-off" periods, letters of medical necessity, and perhaps restrictions on intra-state telemedicine. But like *Zogenix*, each case will be decided on its individual facts, so the specific text and implementation of even traditional regulation should be scrutinized to determine how much it interferes with access to FDA-approved abortion-related drugs.

III. "STOP-SELLING" IMPOSSIBILITY PREEMPTION

A second relevant form of implied FDCA-related preemption exists, grounded in the Supreme Court's impossibility preemption jurisprudence. Claims premised upon a purported state-law duty to stop selling or marketing an FDA-approved product, whether brought by private plaintiffs or by state actors, are preempted.[155] As the Supreme Court explained, "Even in the absence of an express pre-emption provision, the Court has found state law to be impliedly pre-empted where it is 'impossible for a private party to comply with both state and federal requirements.'"[156] While a drug manufacturer "could escape the impossibility of complying with both its federal- and

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hhs.gov/about/news/2022/08/26/hhs-takes-action-strengthen-access-reproductive-health-care-including-abortion-care.html.

[153] H.B. 3, 2022 Gen. Assemb., Reg. Sess. (Ky. 2022), https://apps.legislature.ky.gov/law/acts/22RS/documents/0210.pdf. The revised statute also restricts pharmaceutical "manufacturers" and "distributors" nationwide from selling to "uncertified" Kentucky pharmacies, and to "certify" those manufacturers and distributors who sell even to "certified" pharmacies. KY. REV. STAT. § 216B.204.

[154] Wyeth v. Levine, 555 U.S. 555, 565–66 (2009).

[155] Mut. Pharm. Co. v. Bartlett, 570 U.S. 472 (2013).

[156] *Id.* at 480 (quoting English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990) and citing Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–43 (1963) ("A holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce.")); *see also id.* at 493 ("[T]he FDCA's treatment of prescription drugs includes neither an express pre-emption clause (as in the vaccine context, 42 U.S.C. §300aa-22(b)(1)), nor an express non-pre-emption clause (as in the over-the-counter drug context, 21 U.S.C. §§379r(e), 379s(d)). 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. That federal law forbids [a drug manufacturer] to take actions required of it by state tort law evinces an intent to pre-empt.").

state-law duties by 'choos[ing] not to make [its FDA-approved drug] at all," the Supreme Court has explicitly "reject[ed] this 'stop-selling' rationale as incompatible with our pre-emption jurisprudence."[157] The Supreme Court further explained:

> 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. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be all but meaningless.
>
> The incoherence of the stop-selling theory becomes plain when viewed through the lens of our previous cases. In every instance in which the Court has found impossibility pre-emption, the "direct conflict" between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting.[158]

Because "statutory 'mandate[s]'" are as problematic as tort suits insofar as they "require a manufacturer to choose between leaving the market and accepting the consequences of its actions,"[159] the Supreme Court has analogized the imposition of stop-selling tort liability to a state actor "directly prohibiting the product's sale."[160]

Consequently, "where a State imposes liability based on a balancing of a product's harms and benefits in light of its labeling—rather than directly prohibiting the product's sale—the mere fact that a manufacturer may avoid liability by leaving the market does not defeat a claim of impossibility."[161] Therefore, "[f]or better or for worse, the FDA is the agency that the public has empowered to make authoritative judgments of this kind."[162]

This is particularly true for FDA-approved prescription drugs. Even one of the two dissenting opinions in *Bartlett* expressed discomfort with stop-selling claims in this context, explaining that: "The FDA is responsible for administering the relevant federal statutes. And the question of pre-emption may call for considerable drug-related expertise. Indeed, one might infer that, the more medically valuable the drug, the less likely Congress intended to permit a State to drive it from the marketplace."[163]

As *Bartlett* and its progeny have made clear, "'an outright ban' cannot be a viable alternative to sustain a [state-law] claim."[164] Indeed, following *Bartlett*, courts across the country have almost universally rejected claims "that the defendants should never have sold the FDA-approved formulation of [their drug, because] such claims have been explicitly repudiated by the Supreme Court."[165] In other words, any claim that

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[157] *Id.* at 488.

[158] *Id.* (citation and quotation marks omitted).

[159] *Id.* at 491.

[160] *Id.* at 489 n.5.

[161] *Id.*

[162] Peter H. Schuck, *Multi-Culturalism Redux: Science, Law, and Politics*, 11 YALE L. & POL'Y REV. 1, 39 (1993).

[163] *Bartlett*, 570 U.S. at 494 (but finding conflicting FDA positions on the particular issue before the Court) (Breyer & Kagan JJ., dissenting).

[164] Trisvan v. Heyman, 305 F. Supp. 3d 381, 405 (E.D.N.Y. 2018).

[165] Utts v. Bristol-Myers Squibb Co., 226 F. Supp. 3d 166, 186 (S.D.N.Y. 2016).

the defendant's drug "should have been banned . . . constitutes a 'stop-selling' theory, which courts have consistently found to be preempted by federal law."[166]

A. "Stop-Selling" Claims in Product Liability Litigation

The Sixth Circuit has held that the claim "that defendants should never have sold the[ir] FDA-approved [product] in the first place" was preempted under *Bartlett* as another variant of a "stop-selling rationale."[167] Similarly reflecting *Bartlett*'s holding, preemption of demands based on state law that drug/device manufacturers refrain from selling their FDA-approved products is widespread.

The Fourth Circuit affirmed that state law cannot "require[]" the manufacturer of an FDA-approved drug "to exit the market."[168] Once a drug manufacturer is "authorized to market [its product] with the labeling and formulation specified by the FDA," it "cannot be required to stop selling its product."[169] The court affirmed a decision finding "unavailing [a] Plaintiff's argument that [a defendant] could have simply stopped manufacturing [an FDA-approved drug] and thus avoided violating either federal or state law."[170] The longer discussion in the affirmed opinion (which predated *Bartlett*) was equally unambiguous:

> The Court is aware of no state law duty that would compel generic manufacturers to stop production of a drug that under federal law they have the authority to produce. Nor could such a state law duty exist, as it would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce.[171]

An appellate court in California similarly "conclude[d] that plaintiff's design defect claim that defendants should have withdrawn [the drug] from the market is preempted by the impossibility preemption analysis . . . in *Bartlett*."[172]

Recently, a municipality sought to prohibit the marketing of an entire class of drugs because they were allegedly "inherently dangerous even when taken as directed and when appropriately stored."[173] That claim was "impliedly preempted" because it was grounded on the contention that the defendants "would violate their duty under [state] law by simply marketing [their drug] in its FDA-approved form and with its FDA-approved label. In other words, they would have been required to stop selling" their products.[174]

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[166] Jane Rene' Silver v. Bayer Healthcare Pharm., C.A. No. 2:19-cv-3495-DCN-MHC, 2021 U.S. Dist. LEXIS 188355, at *11 (D.S.C. Sept. 30, 2021) (recognizing that "[t]he Supreme Court has rejected the 'stop-selling' theory as incompatible with preemption jurisprudence because if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be all but meaningless") (quoting *Bartlett*, 570 U.S. at 488) (internal quotation marks omitted).

[167] Yates v. Ortho-Mcneil-Janssen Pharms., Inc., 808 F.3d 281, 300 (6th Cir. 2015).

[168] Drager v. PLIVA USA, Inc., 741 F.3d 470, 476 (4th Cir. 2014).

[169] *Id.* at 477–78.

[170] Gross v. Pfizer, Inc., 825 F. Supp. 2d 654, 659 (D. Md. 2011).

[171] *Id.*

[172] Trejo v. Johnson & Johnson, 13 Cal. App. 5th 110, 147 (2017).

[173] Mayor of Baltimore v. GlaxoSmithKline, LLC, No. 24-C:20-004788, 2022 Md. Cir. Ct. LEXIS 1, at *12 (Md. Cir. Jan. 28, 2022).

[174] *Id.* at *12, *15.

Thus, "any argument that [the defendant] should have stopped selling the drug is unavailing."[175] Numerous other courts have rejected claims that state law can prohibit the sale of FDA-approved drugs.[176]

B. "Stop-Selling" Claims in Non-Product Liability Litigation

"Stop-selling" claims are not limited to product liability litigation. Indeed, the very first FDCA preemption case, *McDermott*, involved a state-law attempt to preclude the marketing of a product bearing an FDA-approved label.[177] The state sought to prohibit the label that the federal predecessor to FDA had approved and to impose criminal sanctions for using the federal label within the state.[178] The Supreme Court held that the state could not exclude products bearing federally approved labels:

> [W]e think to permit such regulation as is embodied in this [state] statute is to permit a state to discredit and burden legitimate Federal regulations of interstate commerce, to destroy rights arising out of the Federal statute which have accrued both to the government and the shipper, and to impair the effect of a Federal law which has been enacted under the Constitutional power of Congress over the subject.[179]

Presaging *Buckman* by nearly a century, *McDermott* held that federal labeling approval was a "measure[] essential to the accomplishment of the purpose," of the FDCA's predecessor statute, and as such "may not be thwarted by state legislation having a direct effect to impair the efficient exercise of such [the federal] means."[180]

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[175] Hernandez v. Aurobindo Pharma USA, Inc., 582 F. Supp. 3d 1192, 1213 (M.D. Fla. 2022).

[176] Beaver v. Pfizer Inc., No. 1:22-CV-00141-MR, 2023 WL 2386776, at *3 (W.D.N.C. Mar. 6, 2023), (holding that states cannot "compel . . . manufacturers to stop production of a drug that under federal law they have the authority to produce"), *aff'd*, No. 23-1297, 2023 WL 4839368 (4th Cir. July 28, 2023); *In re* Zantac (Ranitidine) Prods. Liab. Litig., 548 F. Supp. 3d 1225, 1252–53 (S.D. Fla. 2021); Evans v. Gilead Scis., Inc., No. 20-cv-00123-DKW-KJM, 2020 WL 5189995, at *9–10 (D. Haw. Aug. 31, 2020) (quoting and following *Bartlett*); Javens v. GE Healthcare Inc., C.A. No. 18-1030-RGA-SRF, 2020 WL 2783581, at *17 (D. Del. May 29, 2020) (claim that defendants should have marketed a different product was "clearly preempted by federal law"), *adopted*, 2020 WL 7051642 (D. Del. June 18, 2020); Drescher v. Bracco Diagnostics Inc., No. CV-19-00096-TUC-RM (LCK), 2020 WL 1466296, at *5 (D. Ariz. Mar. 26, 2020); Mahnke v. Bayer Corp., No. 2:19-cv-07271-RGK-MAA, 2019 WL 8621437, at *5 (C.D. Cal. Dec. 10, 2019) (quoting and following *Bartlett*); *In re* Lipitor Atorvastatin Calcium Mktg., 185 F. Supp. 3d 761, 771 (D.S.C. 2016) ("any claims that Defendant should have simply stopped selling the drug to women . . . is preempted"); Utts v. Bristol-Myers Squibb Co., 251 F. Supp. 3d 644, 678 (S.D.N.Y. 2017) (claims that "challenge[] the FDA's approval of . . . [an] indication . . . are preempted"); *In re* Fosamax Prods. Liab. Litig., 965 F. Supp. 2d 413, 420 (S.D.N.Y. 2013) (*Bartlett* "preempted the possibility of [state law] claims based on a [drug manufacturer's] failure to stop selling the product"). *But see* Tobin v. Astra Pharm. Prods., Inc., 993 F.2d 528, 537–38 (6th Cir. 1993) (pre-*Bartlett* decision allowing what was essentially a stop-selling claim; applying Kentucky law).

[177] McDermott v. Wisconsin, 228 U.S. 115, 126–27 (1913) (involving a form of corn syrup). A preemption argument failed in *Savage v. Jones*, 225 U.S. 501, 539 (1912), where a state disclosure requirement did not conflict with the original Pure Food and Drug Act, which was silent on such disclosures.

[178] *McDermott*, 228 U.S. at 133 ("[T]he [state] statute provides that they shall bear the label required by the state law and none other . . . .").

[179] *Id.* at 133–34.

[180] *Id.* at 136–37. *See also* Barnett Bank, N.A. v. Nelson, 517 U.S. 25, 34–35 (1996) (similar non-FDCA stop-selling decision; where a federal statute "explicitly grants . . . an authorization, permission, or power," that grant "does not condition federal permission upon that of the State"); Dowhal v. SmithKline Beecham Consumer Healthcare, 32 Cal. 4th 910, 917–18 (2004) (where plaintiff challenged the failure to put health warnings on nicotine mandated by California law, "[n]otwithstanding language in the FDCA

State-law attempts to ban FDA-approved products have more recently arisen in a variety of other contexts, including under the Lanham Act, FDCA, and antitrust laws, among others.[181] One court held that a competitor could not attack FDA's discretion to allow a product on the market on an emergency basis through a "Memorandum of Discretion."[182] The court analogized the plaintiff's attack on the legality of the defendant's FDA-approved importation of its product to a *Bartlett*-style "stop-selling" claim, because:

> [T]he FDA issued a Memorandum . . . allowing the Defendant temporary permission to import and sell its [drug] product. Notwithstanding the Defendant's permission from the FDA, a viable [trade practices] claim related to the import and sale of [that] product would have nonetheless forced the Defendant "to leave the market or accept tort liability." This is precisely the type of claim that . . . must be preempted.[183]

Consequently, any claim "assert[ing] that the only way to comply with state law would have been for the Defendant to leave the market notwithstanding the Defendant's compliance with the FDA's directives" is preempted.[184]

C. "Stop-Selling" Claims in Litigation Related to Homeopathic Products

FDA has long allowed the marketing and sale of homeopathic products despite considerable questions about their efficacy.[185] Indeed, the FDCA expressly defines a "drug" so as to include "articles recognized in the . . . official Homoeopathic

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exempting Proposition 65 from the preemptive effect of the federal act, when the warning mandated by California law directly conflicts with the one that the federal . . . FDA requires, the federal requirement prevails[]"); People *ex rel*. Lockyer v. Tri-Union Seafoods, LLC, Nos. CGC-01-402975, CGC-04-432394, 2006 Cal. Super. LEXIS 1388, at *201–02 (holding that FDA preempts California Proposition 65 warnings for canned tuna products because it would be impossible for tuna canners to comply with both federal and state law).

[181] *See* Sandoz Pharms. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222 (3d Cir. 1990) (affirming district court's denial of a request for a preliminary injunction against a competitor for allegedly false and deceptive advertising in violation of § 43(a) of the Lanham Act, 15 U.S.C.S. § 1125(a)); Hi-Tech Pharms., Inc. v. Hodges Consulting, Inc., 230 F. Supp. 3d 1323 (N.D. Ga. 2016) (dismissing claims that would require the court to make the "determination of whether a drug is 'new,' and whether it can be lawfully marketed under the FDCA, involves complex issues of history, public safety, and administrative priorities that Congress has delegated exclusively to the FDA.") (quoting JHP Pharms., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 1004 (C.D. Cal. 2014) (same)); Catheter Connections, Inc. v. Ivera Med. Corp., No. 2:14-CV-70-TC, 2014 U.S. Dist. LEXIS 98206, at *20–21 (D. Utah July 17, 2014) ("State law claims relating to medical devices are expressly preempted by the FDCA when state law would require the manufacturer to do something different from or in addition to the requirements of the FDCA and the FDA."); Imagenetix, Inc. v. Frutarom USA, Inc., No. 12CV2823-GPC(WMC), 2013 U.S. Dist. LEXIS 173193, at *13 (S.D. Cal. Dec. 9, 2013) ("The instant case is not a food labeling/misbranding case but a case to determine whether [defendant's product] should be classified a drug, dietary supplement, ODI or NDI, an issue that should be left to the expertise of the relevant agency, the FDA."); Midlothian Labs., L.L.C. v. Pamlab, L.L.C., 509 F. Supp. 2d 1065 (M.D. Ala. 2007), *vacated in part other grounds*, 509 F. Supp. 2d 1095 (M.D. Ala. 2007); Healthpoint, Ltd. v. Stratus Pharms., Inc., 273 F. Supp. 2d 769 (W.D. Tex. 2001); Braintree Labs., Inc. v. Nephro-Tech, Inc., No. 96-2459-JWL, 1997 WL 94237 (D. Kan. Feb. 26, 1997).

[182] Exela Pharma Scis., LLC v. Sandoz, Inc., 486 F. Supp. 3d 1001, 1008 (W.D.N.C. 2020).

[183] *Id.* at 1015 (quoting Drager v. PLIVA USA, Inc., 741 F.3d 470, 479 (4th Cir. 2014)).

[184] *Id.*

[185] Meserey v. United States, 447 F. Supp. 548, 553 (D. Nev. 1977).

Pharmacopoeia of the United States."[186] Nonetheless, in 2015, private plaintiffs, wielding state-law causes of action, attempted to enjoin the continued sale of homeopathic products market despite FDA allowing them to be sold.[187] They were not successful in their efforts:

> to change the labeling requirements of Defendant's homeopathic medication [to one that] conflicts with federal policy [because it is] impliedly preempted . . . [and] allowing the claim for injunctive relief to go forward would undermine the purpose for which Congress enacted the uniformity provision and thwart the Food and Drug Administration's ability to carry out its oversight of marketing of homeopathic products.[188]

D. Application to State Regulation of Medication Abortion

Bartlett's "analysis suggests that FDA drug approval would impliedly preempt state positive law as well."[189] Applying the *Bartlett*-based stop-selling rationale—"a straightforward application of pre-emption law"[190]—to state efforts to prohibit or restrict abortion, it is evident that any attempt to prohibit the sale of an FDA-approved drug would be subject to a substantial preemption challenge. What state law cannot do indirectly, through common-law litigation, it can certainly not do directly, through some "statutory 'legal mandate.'"[191] "[I]f the relatively more attenuated command of design defect scrutiny in tort law created an actual conflict with federal law governing FDA-approved drugs, then surely an outright sales prohibition imposed by state officials would do so."[192]

A state-law decree that "a party contravenes the law" by manufacturing, selling, prescribing, or using an FDA-approved drug for an FDA-approved indication is preempted because, in such a case, "state law forbids the use" of a product that has received FDA approval, thereby requiring the actor "to choose between leaving the market and accepting the consequences of its actions (in the form of a fine or other sanction)."[193]

By rendering the legal sale of an FDA-approved product for an FDA-approved indication, impossible under state law, a state's outright prohibition of an abortion-related drug should fall under *Bartlett*'s stop-selling preemption rationale.

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[186] 21 U.S.C. § 321(g)(1). *See* 21 U.S.C. § 351(b) (when a drug "is labeled and offered for sale as a homoeopathic drug, . . . it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States"); 21 U.S.C. § 360eee(13) (defining "product" as including "homeopathic drugs marketed in accordance with applicable guidance under this Act").

[187] Herazo v. Whole Foods Mkt., Inc., No. 14-61909-CIV-MORENO, 2015 WL 4514510 (S.D. Fla. July 23, 2015).

[188] *Id.* at *16.

[189] *See* Noah, *supra* note 99, at 34.

[190] Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 493 (2013).

[191] *Id.* at 491.

[192] *See* Noah, *supra* note 99, at 35.

[193] *Bartlett*, 570 U.S. at 490, 491 (citations omitted).

IV. A ROLE FOR EXPRESS PREEMPTION—APPLICATION TO STATE REGULATION OF OVER-THE-COUNTER EMERGENCY CONTRACEPTION

The FDCA provides for national "uniformity for nonprescription drugs" to guarantee consistent access to over-the-counter (OTC) medicines.[194] Therefore, federal law may preempt state restrictions that interfere with access to OTC medications, including regulations that affect emergency contraception.[195] Although use of emergency contraceptive drugs (e.g., Plan B® (levonorgestrel), 1.5mg) is not considered an "abortion" according to prevailing medical and legal standards,[196] due to research limitations, "the possibility of a postfertilization event cannot be ruled out."[197] For that reason, various states restricting abortion also have laws that may interfere with access to emergency contraception. Thus, a similar conflict between state regulations on emergency contraception and the availability of FDA-approved drugs—this time involving OTC drugs—likewise implicates preemption.[198]

OTC drugs differ from prescription drugs because patients will typically access an OTC drug without a healthcare provider's involvement.[199] OTC drugs have been regulated by FDA through a "monograph" issued in notice-and-comment rulemaking,

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[194] 21 U.S.C. § 379r.

[195] *Id.* (preventing a "State or political subdivision of a State" from implementing a requirement "that relates to the regulation of a drug that is not subject to the requirements of [physician-prescribed or veterinary drugs]" and that is "different from or in addition to, or that is otherwise not identical with, a requirement under this Act [21 U.S.C.S. §§ 301 *et seq.*], the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 *et seq*.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq*.)[]" with certain enumerated exceptions).

[196] In 2022, "FDA determined the current science supports a conclusion that Plan B One-Step works by inhibiting or delaying ovulation and the midcycle hormonal changes. The evidence also supports the conclusion that there is no direct effect on fertilization or implantation." *See Plan B One-Step (1.5 mg levonorgestrel) Information*, U.S. FOOD & DRUG ADMIN. (Dec. 23, 2022), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/plan-b-one-step-15-mg-levonorgestrel-information. *See also* Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2276 (2022) (distinguishing abortion from existing precedent on pre-viability contraception); *see* Gabriela Noé, Horacio B. Croxatto, Ana María Salvatierra, Verónica Reyes, Claudio Villarroel, Carla Muñoz, Gabriela Morales & Anita Retamales, *Contraceptive Efficacy of Emergency Contraception with Levonorgestrel Given Before or After Ovulation*, 81 CONTRACEPTION 414 (May 2010), https://pubmed.ncbi.nlm.nih.gov/20399948/ (concluding that the active ingredient of Plan B and similar emergency contraceptives "prevents pregnancy only when taken before fertilization of the ovum has occurred"); *see also* Pam Belluck, *Abortion Qualms on Morning-After Pill May Be Unfounded*, N.Y. TIMES (June 5, 2012).

[197] U.S. GOV'T ACCOUNTABILITY OFF., GAO-06-109, FOOD AND DRUG ADMINISTRATION: DECISION PROCESS TO DENY INITIAL APPLICATION FOR OVER-THE-COUNTER MARKETING OF THE EMERGENCY CONTRACEPTIVE DRUG PLAN B WAS UNUSUAL 13 (Nov. 2005), https://www.gao.gov/assets/gao-06-109.pdf.

[198] This Article does not address other possible federal law conflicts. *Cf. Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services*, U.S. DEP'T OF HEALTH & HUM. SERVS. (July 14, 2022), https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html.

[199] *E.g.*, Robinson v. McNeil Consumer Healthcare, 615 F.3d 861, 868 (7th Cir. 2010). "Drugs sold over-the-counter are deemed sufficiently safe to be dispensed directly to the public accompanied only by directions for proper use, and relevant warnings printed on the packages." Swayze v. McNeil Laboratories, Inc., 807 F.2d 464, 466 (5th Cir. 1987).

which specifies the conditions under which a drug is "generally recognized as safe and effective" (GRASE) for each active ingredient.[200] Healthcare providers generally are not involved for OTC drugs taken as directed in a monograph, in part, because OTC drugs are "adequately labeled so that consumers can self-diagnose the condition, self-select the medication, and self-manage the condition."[201] Some OTC drugs, referred to as "behind the counter" (BTC) drugs, are available without a prescription, but require a purchaser to present identification or other information to verify their entitlement to access a given drug.[202]

Originally, FDA approved Plan B as a prescription drug in 1999.[203] In 2006, FDA approved Plan B for use without a prescription for women ages eighteen and older, and the proof of age requirement rendered it functionally a BTC drug.[204] Three years later, FDA expanded BTC access to women ages seventeen or older, in response to a court order following a politically fraught decision that pitted career scientists (concerned with safety and efficacy) against political appointees (concerned with youth promiscuity).[205] Finally, in 2013, partially in response to another court order, FDA approved Plan B, and later generic equivalents, for OTC use for women capable of bearing children, with no age restriction.[206] Even with OTC status though, some women obtain a prescription for Plan B, largely for insurance coverage reasons.[207]

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[200] *See* Goldstein v. Walmart, Inc., No. 22-cv-00088 (LJL), 2022 U.S. Dist. LEXIS 196743, at *7–8 (S.D.N.Y. Oct. 28, 2022). Well after FDA approval of currently available emergency contraception, Congress overhauled the monograph system, replacing rulemaking with an administrative order process. *See* Final Administrative Orders for Over-the-Counter Monographs; Availability, 86 Fed. Reg. 52,474, 52,474–75 (Sept. 21, 2021) (describing new process).

[201] CONG. RES. SERV., R46985, FDA REGULATION OF OVER-THE-COUNTER (OTC) DRUGS: OVERVIEW AND ISSUES FOR CONGRESS 1 (Dec. 10, 2021), https://sgp.fas.org/crs/misc/R46985.pdf.

[202] *See* W. Steven Pray & Gabriel E. Pray, *Behind-the-Counter Products: A Third Class of Drugs*, U.S. PHARMACIST (Sept. 20, 2011), https://www.uspharmacist.com/article/behind-the-counter-products-a-third-class-of-drugs. BTC status is ordinarily a state-law issue, to prevent drug diversion or shoplifting, not an FDA classification. *Id.* Indeed, FDA has generally disclaimed authority to create a BTC status but continues to regulate these products as OTC drugs.

[203] Ass'n of Am. Physicians & Surgs., Inc. v. FDA, 539 F. Supp. 2d 4, 10 (D.D.C. 2008), *aff'd*, 358 F. Appx. 179 (D.C. Cir. 2009).

[204] Janice Hopkins Tanne, *FDA Finally Approves Plan B—But with Restrictions*, 333 BMJ 7566 (Sept. 2, 2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1557972/#. *See also* Tummino v. Hamburg, 936 F. Supp. 2d 162, 183 (E.D.N.Y. 2013) (ultimately rejecting FDA authority to impose an age-restricted BTC designation).

[205] Janice Hopkins Tanne, *FDA Agrees to Ease Restrictions on Emergency Contraceptive*, 338 BMJ 1756 (Apr. 28, 2009), https://www.bmj.com/content/338/bmj.b1756; *see also id.* (requiring modification of the age limit); Tummino v. Torti, 603 F. Supp. 2d 519, 523–24 (E.D.N.Y. 2009) (same; finding political interference); Tummino v. Von Eschenbach, 427 F. Supp. 2d 212, 232–34 (E.D.N.Y 2006) (ordering discovery into political interference at FDA).

[206] Michael McCarthy, *US Court Lifts Restrictions on Some Emergency Contraceptives*, 346 BMJ f3760 (June 10, 2013), https://www.bmj.com/content/346/bmj.f3760.

[207] *See, e.g.*, *What's the Plan B Morning-After Pill?*, PLANNED PARENTHOOD, https://www.plannedparenthood.org/learn/morning-after-pill-emergency-contraception/whats-plan-b-morning-after-pill ("If you have health insurance or Medicaid, there's a good chance you can get Plan B for free—you just have to ask your nurse or doctor for a prescription so your health insurance will cover them (even though you don't need a prescription to buy these types of morning-after pills over-the-counter).").

Today, the FDA-approved OTC status for "Plan B One-Step" addresses the risks and benefits of using the drug to prevent pregnancy.[208] The FDA press release accompanying Plan B's approval as an OTC drug noted that the drug "will not stop a pregnancy when a woman is already pregnant and there is no medical evidence that the product will harm a developing fetus[,]" which is consistent with the drug's monograph.[209] The features of drugs governed by the Plan B approval most salient to preemption analysis are: (1) non-interference with pregnancies, and (2) OTC availability based on FDA-approval, which accounts for indications for use, contraindications, and various risks including overdose and other-drug interactions.

The FDCA has an express preemption clause applicable to "nonprescription" OTC drugs.[210] For these drugs, "no State or political subdivision" may create a law to regulate a non-prescription drug "that is different from or in addition to, or that is otherwise not identical with" regulations promulgated by the federal government.[211] This statutory requirement for uniform availability of OTC drugs applies to state regulations that restrict access to emergency contraception beyond what FDA requires,[212] however, this general rule is subject to a series of exceptions on which states may attempt to rely to maintain restrictions on emergency contraception. State regulations on OTC drugs that go beyond FDA regulations may seek to avoid preemption when a regulation falls "*outside the scope* of federal requirements" relevant to those drugs.[213] Courts will determine the scope of federal requirements by reference to the OTC drug's FDA-approved monograph.[214]

States may also regulate OTC drugs in accordance with five enumerated exceptions to FDCA preemption.[215] First, states may apply to FDA for approval of regulations specific to an OTC drug, in order to protect "an important public interest that would otherwise be unprotected," provided those regulations do not violate other federal law or unduly burden interstate commerce.[216] Second, the uniformity requirement does not

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[208] While many OTC drugs are monograph products, Plan B is not, FDA having changed its status through an NDA supplement. *See* CTR. FOR DRUG EVALUATION & RSCH., U.S. FOOD & DRUG ADMIN., APPROVAL PACKAGE FOR PLAN B ONE-STEP (Apr. 30, 2013), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/021998Orig1s002.pdf.

[209] Jennifer Levin, *FDA Approves Plan B One-Step Emergency Contraceptive for use Without a Prescription for all Women of Child-Bearing Potential*, FIERCE PHARMA (June 20, 2013), https://www.fiercepharma.com/pharma/fda-approves-plan-b-one-step-emergency-contraceptive-for-use-without-a-prescription-for-all.

[210] 21 U.S.C. § 379r.

[211] *Id.* § 379r(a).

[212] Unlike implied preemption, any presumption against preemption has been abolished in express preemption cases. Puerto Rico v. Franklin Cal. Tax-Free Trust, 579 U.S. 115, 125 (2016) ("because the statute contains an express preemption clause, we do not invoke any presumption against preemption but instead focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent") (citation and quotation marks omitted).

[213] *See* Goldstein v. Walmart, Inc., No. 22-cv-00088 (LJL), 2022 U.S. Dist. LEXIS 196743, at *24 (S.D.N.Y. Oct. 28, 2022) (quoting, Bimont v. Unilever U.S., Inc., No. 14-CV-7749 (JPO), 2015 U.S. Dist. LEXIS 119908 (S.D.N.Y. Sept. 9, 2015)) (emphasis added).

[214] *Id.* at *31–32.

[215] *Id.*

[216] 21 U.S.C. § 379r(b). Little case law interprets the meaning of "important public interest that would otherwise be unprotected." This exception requires states to apply to the federal government in order to raise such an interest. To date, no state has applied for special treatment of OTC emergency contraception.

apply to a regulation "that relates to the practice of pharmacy" or "that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug."[217] Third, states may impose restrictions on OTC drugs that have not received final federal approval, but only if those restrictions are not "relate[d] to the same subject as" existing federal regulation.[218] Fourth, federal law guaranteeing access to OTC drugs does not necessarily preempt related state product liability law.[219] Fifth, and finally, states are permitted to adopt laws that are "identical to a requirement" of FDA.[220] To determine whether state laws on access to emergency contraception are preempted, a necessary first step would be to ask whether a given state restriction fits into one of these enumerated exceptions to national uniformity of access to OTC drugs. The second exception here is most relevant to state regulation of OTC emergency contraception, given the prevalence of state regulation specific to pharmacist and pharmacy practice.

Pharmacy Conscience Clauses: Some state regulations on OTC emergency contraception permit pharmacists or pharmacies to choose not to carry or dispense those drugs. These state regulations are commonly known as conscience clauses, and may fit within a federal concession to traditional state power to regulate "the practice of pharmacy" and licensure standards for administration of drugs.[221] However, emergency contraception is not included in the federal conscience clause statute.[222] Therefore, state conscience clauses that affect emergency contraception are "in addition to" laws passed by the federal government.[223] Whether these laws are preempted will depend on whether they fit into an exception to the national uniformity requirement.[224] Since the mechanism of action for Plan B and other types of contraceptives is similar, a conscience clause defense is weakened to the extent

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[217] *Id.* § 379r(c)(1). This subsection has never been addressed, or even cited, in any judicial opinion. Whether subsection (c)(1) would permit a state to require a prescription for a drug, like Plan B, that FDA has specifically determined should be available without a prescription is uncertain, but at most that exception is only to express federal preemption. Even if § 379r(c)(1) precludes express preemption, a state restriction purporting to impose prescription-only status on a drug, like Plan B, for which FDA mandates OTC status, would be in direct conflict with federal law, and thus could be subject to implied preemption. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 352 (2001) ("neither an express pre-emption provision nor a saving clause 'bar[s] the ordinary working of conflict pre-emption principles.'") (quoting Geier v. Am. Honda Motor Co., 529 U.S. 861, 869 (2000)).

[218] 21 U.S.C. § 379r(d); *see also* Delarosa v. Boiron, Inc., 818 F. Supp. 2d 1177 (C.D. Cal. 2011) (interpreting 21 U.S.C. § 379r(d) and holding that claims for injury from homeopathic products are not preempted where those drugs were not subject to federal law establishing standards for safety and efficacy).

[219] 21 U.S.C. § 379r(e); *see also* Valdes v. Optimist Club of Suniland, Inc., 27 So. 3d 689 (Fla. App. 2009) (reversing dismissal of a Florida tort claim premised on a medication's inadequate warnings of heat stroke).

[220] 21 U.S.C. § 379r(f); *see also* Anglin v. Edgewell Pers. Care Co., No. 4:18-CV-00639-NCC, 2018 U.S. Dist. LEXIS 207304 (E.D. Mo., Dec. 7, 2018) (upholding state law claims related to FDA-regulated sunscreen labels "to the extent Plaintiffs' state law claims do not seek to impose any requirements on Defendants beyond those which federal law already requires").

[221] 21 U.S.C. § 379r(c)(1).

[222] 42 U.S.C. § 300a-7 (prohibiting public officials from requiring individuals to participate in sterilization or abortion procedures which contradict religious beliefs or moral convictions).

[223] 21 U.S.C. § 379r(a). As discussed *supra*, note 217, to the extent that § 379r(c)(1) places the practice of pharmacy outside of express federal preemption, conscience clauses could still be subject to implied preemption, should they directly conflict with FDA requirements.

[224] 21 U.S.C. § 379r(a).

emergency contraceptives are subject to special rules not applicable to other contraceptives. Note that conscience clauses vary from state to state, so some may be more resistant to preemption than others:

- **Generalized Conscience Clauses**: States like Illinois take a broad approach to conscience clauses, offering a broad exemption that is not specific to abortion or any particular medication.[225] More generalized conscience clauses may be reconciled with state-specific precedent on reproductive health and/or the obligations of pharmacies, as occurred in Illinois.[226]
- **Drug-Specific Conscience Clauses**: States like Idaho specifically include emergency contraception in their conscience clauses.[227] These drug-specific clauses are certainly different from, or could conflict with, regulations promulgated by the federal government and, for drugs like Plan B that are available over the counter, do not implicate "the practice of pharmacy" when a pharmacist is not involved in providing the drug. Thus, state conscience clauses which provide pharmacists with discretion not to dispense a drug are vulnerable to preemption to the extent a pharmacist is not involved in providing the medication (as is almost always true of Plan B, when dispensed over the counter at the front-of-store by a clerk rather than pharmacy staff).
- **Illusory Conscience Clauses**: Conscience exemptions in certain states do not actually cover emergency contraception, which potentially leaves pharmacists or pharmacies that refuse to dispense Plan B liable for unlawfully obstructing availability of an OTC drug. For example, South Dakota's statute allows pharmacists to refuse to dispense drugs that "(1) Cause an abortion; or (2) Destroy an unborn child [from fertilization until live birth.]"[228] This regulation clearly does not apply to emergency contraception, as indicated by the FDA-approved monograph for Plan B. While some view South Dakota's conscience clause as relating to emergency contraceptives,[229] it probably would not protect pharmacists who refuse to dispense emergency contraception.[230] Simply put, conscience clauses related to abortion do not *ipso facto* relate to emergency contraception.

Restriction of Reimbursement: States like Texas and North Carolina exclude coverage of contraceptives from the contraceptive coverage mandate of their family

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225 745 ILL. COMP. STAT. ANN. 70/4.

226 *See* Morr-Fitz, Inc. v. Quinn, 976 N.E.2d 1160 (Ill. App. 2012).

227 IDAHO CODE § 18-611(2).

228 S.D. CODIFIED LAWS § 36-11-70.

229 *See* Heidi Bell Gease, *S.D. Law Gives Pharmacists a 'Conscience Clause'*, RAPID CITY J., Dec. 16, 2007; *see also* Joshua T. Shaw, *Conceiving Plan B: A Proposal to Resolve the Conflict Between Women and Conscientiously Objecting Pharmacists over Access to Emergency Contraceptives*, 16 WASH. & LEE J. CIV. RTS. & SOC. JUST. 563 (2010).

230 *See* discussion *supra* note 196 (differentiating pre-fertilization emergency contraception from post-fertilization abortions).

planning programs.[231] These exclusions were upheld in federal court, meaning that private entities may take advantage of state laws to carve-out emergency contraceptives from their insurance coverage, notwithstanding a general contraceptive coverage mandate.[232]

Medication-Specific Restrictions and Prohibitions: No state has yet categorically banned or restricted access to emergency contraception like Plan B. In the event a state were to prohibit sale or use of emergency contraception generally, the precedents discussed above would weigh against that regulation, given the clear FDCA national mandate to ensure consistent access to prescription drugs, and that *Dobbs* did not contemplate a state interest in potential pregnancies prior to implantation.

V. BALANCING STATE AUTHORITY OVER THE PRACTICE OF MEDICINE AGAINST FEDERAL OVERSIGHT OF DRUG APPROVAL, MARKETING, AND DISTRIBUTION

Finally, any discussion of FDCA-related preemption of state-law restrictions on the availability of abortifacient drugs must account for historic state police power over the practice of medicine. Regulation of, and authority over, public health is a delicate balance between state and federal power: "The entire enterprise of drug regulation is quite complex because both the state and federal government are regulating the same activities, but from very different inherent powers."[233] Although the "regulation of health and safety matters is primarily, and historically, a matter of local concern,"[234] "there is no question that the Federal Government can set uniform national standards in these areas."[235] As such, "[t]he police powers [of the states] authorize government to exercise compulsory powers for the common good, but the state must act in conformity with constitutional and statutory constraints."[236]

A. Relevant Federal Regulation of the Intended Use of Drugs

The original 1906 predecessor to the FDCA "prohibited the manufacture or interstate shipment of adulterated or misbranded drugs" and "supplemented the protection for consumers already provided by state regulation and common law liability."[237] "In the 1930s, Congress became increasingly concerned about unsafe

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[231] 1 TEX. ADMIN. CODE § 382.113(b); *Family Planning Program Policy Manual: 5600, Family Planning and Contraceptive Services*, TEX. HEALTH & HUM. SERVS. COMM'N (eff. Apr. 1, 2022), https://www.hhs.texas.gov/handbooks/family-planning-program-policy-manual/5600-family-planning-contraceptive-services; N.C. GEN. STAT. 58-3-178(c)(4) (1999).

[232] *See, e.g.*, Catholic Benefits Ass'n LCA v. Sebelius, 24 F. Supp. 3d 1094, 1103–04 (W.D. Okla. 2014) (holding that state law exempted a private religious entity from covering emergency contraceptives).

[233] Jennifer S. Bard, *How Public Health Informed Lawmaking Would Address the Rising Synthetic Opioid Death Toll*, 87 BROOK. L. REV. 657, 679 (2022).

[234] Hillsborough Cnty. v. Automated Med. Laboratories, Inc., 471 U.S. 707, 719 (1985).

[235] Gonzales v. Oregon, 546 U.S. 243, 271 (2006) (citation omitted); *cf.* Gibbons v. Ogden, 22 U.S. 1, 210 (1824) ("the validity of [the states' police power] depends on their interfering with, and being contrary to, an act of Congress passed in pursuance of the constitution").

[236] Lawrence O. Gostin, *Law and the Public's Health*, 21 ISSUES SCI. & TECH., Spring 2005.

[237] Wyeth v. Levine, 555 U.S. 555, 566 (2009).

drugs and fraudulent marketing, and it enacted the [FDCA]."[238] Its "most substantial innovation was its provision for premarket approval of new drugs. It required every manufacturer to submit a new drug application . . . to the FDA for review."[239] In 1962, Congress amended the FDCA to require that manufacturers "demonstrate that its drug was 'safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling' before it could distribute the drug."[240]

Through the FDCA, Congress charged FDA 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."[241] Congress requires FDA to "protect the public health" by ensuring that "drugs are safe and effective."[242] FDA accomplishes this by, among other things, regulating the labeling of prescription drugs.[243] Over the years, FDA's authority was expanded to include the regulation of advertising and promotion of drugs[244] as well as medical devices.[245]

In order for a prescription medical product to be marketed, it must have FDA approval or clearance to be labeled for at least one "intended use."[246] FDA review "shall be based upon the proposed labeling submitted."[247] Intended use is significant because the "FDA's review of a [product's] safety and effectiveness [is] not universal[,] [but] focused only on the intended use specified by a manufacturer."[248] In other words, "pharmaceuticals are studied for certain indications for which they are determined to be safe and effective. No other indication is approved because the drug is not known to be either safe or effective for any other purpose."[249]

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[238] *Id.* The 1938 Act imposed only safety-related drug mandates and did not address efficacy. *See, e.g.*, Cutler v. Hayes, 818 F.2d 879, 883 (D.C. Cir. 1987).

[239] *Levine*, 555 U.S. at 566. The 1962 Act both created the current premarket approval process for new drugs and required that applicants for approval establish the efficacy of their products. *Id.* at 567; *see* United States v. Rutherford, 442 U.S. 544, 552 & n.8 (1979) (detailing major provisions of the 1962 Act).

[240] *Levine*, 555 U.S. at 567 (internal citation omitted).

[241] 21 U.S.C. § 393(b)(1).

[242] *Id.* § 393(b)(2)(B).

[243] *Id.* § 321(p)(1) (2021) (defining "new drug" as any substance covered by the FDCA not "generally recognized[] among experts . . . as safe and effective for use under the condition prescribed . . . in the labeling"); *see* United States v. Undetermined Quantities of Various Articles of Drug . . . Equidantin Nitrofurantoin Suspension . . . , 675 F.2d 994, 998 (8th Cir. 1982) (quoting United States v. Premo Pharm. Laboratories, Inc., 511 F. Supp. 958, 962 (D.N.J. 1981) (describing evolution of FDCA and its regulation of drug labeling)).

[244] Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962). "Behind the 1962 amendments were concerns that doctors could not adequately evaluate frequently misleading claims by drug manufacturers without a body of objective, reliable information." United States v. Caronia, 703 F.3d 149, 178 (2d Cir. 2012).

[245] Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976).

[246] 21 C.F.R. §§ 201.57(c)(2) (2021), 807.92(a)(5) (2021).

[247] 21 U.S.C. § 360c(i)(1)(E)(i) (2021) (devices); *see* 21 U.S.C. § 355(d) (2021) (FDA drug approvals are based on review of the "conditions prescribed, recommended, or suggested in the proposed labeling").

[248] De La Paz v. Bayer Healthcare LLC, 159 F. Supp. 3d 1085, 1093 (N.D. Cal. 2016) (citation omitted) (internal quotation marks omitted); *see* Weinreb v. Xerox Bus. Servs., LLC, 323 F. Supp. 3d 501, 507 (S.D.N.Y. 2018) (FDA drug approval is "for one type of use and/or for one condition").

[249] Mary J. Davis, *Time for a Fresh Look at Strict Liability for Pharmaceuticals*, 28 CORNELL J.L. & PUB. POL'Y 399, 435 (2019) (footnote omitted).

Ultimately, "[f]ederal regulation of medical products is grounded in the introduction of [articles] in interstate commerce for commercial distribution, not use by physicians. This concept forms the basis for the 'practice of medicine' doctrine, which maintains that FDA lacks authority under the FDCA to regulate patient treatment decisions made by licensed physicians."[250] The FDCA expressly states, "Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."[251] As such, "FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals."[252] That is not to say that the federal government has no authority to ensure adequate patient care. FDA does regulate off-label use indirectly, through REMS that involve "additional mechanisms to assure access."[253]

B. The Contours of Off-Label Use

1. Authority Over Off-Label Use

FDA only approves products in the context of labeling for their intended use as submitted by the manufacturer; "[i]f the FDA grants an approval, it means the agency has determined that the benefits of the product outweigh the risks for the intended use."[254] When a physician uses a drug consistent with its FDA-approved label, that is considered to be on-label use. If a healthcare provider uses FDA-approved products in any way beyond the single intended use submitted by the manufacturer—such as utilizing methotrexate as an abortifacient[255]—it is ordinarily outside the scope of FDA regulation[256] and is considered to be "off-label" use.[257] Off-label use is defined as "the prescription of drugs for indications, in dosages, and following treatment protocols different from those expressly approved by the FDA."[258] It also includes "prescriptions of the drug for a condition not indicated on the label, treating an indicated condition at a different dose or frequency than specified on the label, or treating a different

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[250] John J. Smith, *Physician Modification of Legally Marketed Medical Devices: Regulatory Implications Under the Federal Food Drug, and Cosmetic Act*, 55 FOOD & DRUG L.J. 245, 251 (2000).

[251] *Id.* at 252; 21 U.S.C. § 396.

[252] Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001) (citation omitted). While *Buckman* dealt with medical devices, a similar practice-of-medicine exemption exists for prescription drugs. *See* 21 C.F.R. § 312.2(d) ("This part does not apply to the use in the practice of medicine for an unlabeled indication of a new drug product . . . or of a licensed biological product.").

[253] 21 U.S.C. § 355-1(f)(6).

[254] *Is It Really 'FDA Approved?'*, U.S. FOOD & DRUG ADMIN. (May 10, 2022), https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved; *New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN. (Jan. 21, 2022), https://www.fda.gov/drugs/types-applications/new-drug-application-nda ("The law is intended to assure consumers . . . that drugs and devices are safe and effective for their intended uses[.]").

[255] *See* Potts, *supra* note 21 (discussing this off-label use of methotrexate).

[256] *See* 21 U.S.C. §§ 355-1(f)(6), 352(y) (discussing FDA regulation of off-label use through REMS).

[257] *E.g.*, Stiens v. Bausch & Lomb, Inc., 626 S.W.3d 191, 195 (Ky. Ct. App. 2020), *review denied* (Ky. Aug. 18, 2021).

[258] Cordray v. Planned Parenthood Cincinnati Region, 911 N.E.2d 871, 878 (Ohio 2009) (citation omitted).

patient population than approved by the FDA."[259] In addition, "medical practice guidelines, and thus the standard of care, revolve around medical decisions that are 'medically necessary' and 'evidence-based,' whereas the distinction between on-label and off-label is made solely through the FDA approval process."[260]

FDA does not regulate off-label medical practice.[261] Indeed, "Congress has not only declined to prohibit off-label uses; it has actually permitted, and regulated, a degree of involvement by drug and device manufacturers in getting the word out concerning such uses of their products."[262] In fact, "courts and . . . FDA have recognized the propriety and potential public value of unapproved or off-label drug use."[263] The FDCA "expressly contemplates the possibility that physicians may use [approved products] for unapproved purposes."[264] And FDA acknowledges that "a health care professional can generally choose to use or prescribe an approved or cleared medical product for an unapproved use, if the off-label use is appropriate based on his or her judgment."[265]

The benefits of off-label use are acknowledged, and even supported, by courts and commentators. In *Buckman*, the Supreme Court acknowledged that "off-label use is generally accepted" under the law as a "necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."[266] In clinical practice, "new uses or dosing regimens often become widespread and well accepted long before they are reflected in the labeling."[267] Indeed, "a life-threatening or terminal medical condition may motivate a health care professional to give any

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[259] Ironworkers Loc. Union 68 v. AstraZeneca Pharms., LP, 634 F.3d 1352, 1356 n.4 (11th Cir. 2011); *see* Amarin Pharma, Inc. v. FDA, 119 F. Supp. 3d 196, 202 (S.D.N.Y. 2015).

[260] Katherine A. Blair, *In Search of the Right Rx: Use of the Federal False Claims Act in Off-Label Drug Promotion Litigation*, 23 HEALTH L. 44, 45 (2011) (footnote omitted).

[261] *See* Beck, *supra* note 31, at 18–19, n.21 (collecting authority).

[262] Scoggins v. Boston Sci. Corp., No. 07-4049, 2010 Mass. Super. LEXIS 2988, at *21 (Mass. Super. Ct. Oct. 18, 2010).

[263] United States *ex rel*. Polansky v. Pfizer, Inc., 822 F.3d 613, 615 (2d Cir. 2016) ("[t]he physician is permitted to issue off-label prescriptions") (quoting United States v. Caronia, 703 F.3d 149, 153 (2d Cir. 2012)).

[264] Shuker v. Smith & Nephew, PLC, 885 F.3d 760, 766–67 (3d Cir. 2018); *see* United States *ex rel*. King v. Solvay Pharms., Inc., 871 F.3d 318, 328 (5th Cir. 2017) ("FDA does not restrict physicians from prescribing an otherwise FDA-approved drug for an off-label use."); *Caronia*, 703 F.3d at 166 ("FDA's . . . approval process generally contemplates that approved [products] will be used in off-label ways."); White v. Medtronic, Inc., 808 F. App'x 290, 296 (6th Cir. 2020) ("the FDCA expressly contemplated the off-label use of medical devices") (applying Michigan law); *In re* Smith, 401 F. Supp. 3d 538, 553 (D. Md. 2019) (citing 21 U.S.C. § 396 that "implicitly endorses off-label use of devices").

[265] U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: DISTRIBUTING SCIENTIFIC AND MEDICAL PUBLICATIONS ON UNAPPROVED NEW USES—RECOMMENDED PRACTICES, REVISED DRAFT GUIDANCE 6 (Feb. 2014), https://www.fda.gov/media/88031/download; *see Understanding Unapproved Use of Approved Drugs "Off Label,"* U.S. FOOD & DRUG ADMIN. (Feb. 5, 2018), www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label (stating that "healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate").

[266] Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350–51 (2001) (footnote omitted).

[267] Comm. On Drugs, Am. Acad. of Pediatrics, *Uses of Drugs Not Described in the Package Insert (Off-Label Uses)*, 110 PEDIATRICS 181, 182 (2002); *see* Anna B. Laakmann, *When Should Physicians Be Liable for Innovation?*, 36 CARDOZO L. REV. 913, 939 (2015) ("In some cases, off-label use constitutes the standard of care.").

treatment that is logical and available, whether approved by the FDA or not."[268] Accordingly, "[p]hysicians may, in their professional judgment, prescribe a drug for a purpose other than that for which it has been approved by the FDA."[269]

Off-label use can be a form of medical "progress" through clinical practice:

> [H]uman progress is not static: medical research and advances do not stop upon a particular drug's approval by the FDA. Researchers continue to perform clinical trials, doctors continue to gain experience, and widespread use of a particular treatment allows the medical community to collect data about side effects, alternative doses, and potential new uses for treatments.[270]

The same applies to medication used for abortion: courts acknowledged that, what was an off-label use of mifepristone was as safe—even safer than—its original FDA-approved on-label use for the same indication. Off-label use of mifepristone became so widely accepted that "an off-label protocol was developed[.]"[271] Clinical experience supported the newer off-label "protocol" for mifepristone-mediated medication abortion:

> [T]he evidence shows that there are no significant health-related problems which occur by utilizing the current [off-label] protocol. In fact, the sixteen-year-old 2000 protocol would impose more health risks and cost related burdens than the current protocol. The evidence strongly indicates adherence to the outdated protocol would make medication abortion more costly, less effective, and more prone to negative side effects.[272]

In 2016, FDA finally approved this standard-of-care regimen.[273] While FDA's review of a particular product may lag, off-label use ensures that patients obtain the

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[268] Christopher M. Wittich, Christopher M. Burkle & William L. Lanier, *Ten Common Questions (and Their Answers) About Off-Label Drug Use*, 87 MAYO CLINIC PROC. 982, 982 (2012).

[269] T.H. v. Novartis Pharms. Corp., 407 P.3d 18, 24 n.1 (Cal. 2017) (citing *Buckman Co.*); *see* Smith v. Surgery Ctr. at Lone Tree, LLC, 2020 COA 145M, 33 n.2 (Colo. App. 2020) ("FDA generally does not regulate how physicians use approved drugs.") (quoting *Caronia*, 703 F.3d at 153), *cert. denied*, No. 20SC917, 2021 Colo. LEXIS 258 (Colo. Apr. 12, 2021); Caltagirone v. Cephalon, Inc., 190 A.3d 596, 598 (Pa. Super. Ct. 2018) (stating that "physicians may prescribe medications for purposes other than those approved by the FDA") (emphasis omitted); Blazoski v. Cook, 787 A.2d 910, 920 (N.J. App. Div. 2002) ("[P]hysicians have the right, exercising reasonable medical judgment, to use medical devices for off-label purposes that are not FDA approved, provided that the FDA has approved the device for some other purpose.") (citation omitted); Klein v. Biscup, 673 N.E.2d 225, 231 (Ohio Ct. App. 1996) (ruling that "the decision whether or not to use a drug for an off-label purpose is a matter of medical judgment not of regulatory approval"); Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 197 (4th Cir. 2001**)** ("Once the FDA has cleared a [product] for introduction into the stream of commerce, physicians may use [it] in any manner they determine to be best for the patient, regardless of whether the FDA has approved [it] for this usage.") (citation omitted).

[270] Cline v. Okla. Coal. for Reprod. Just., 313 P.3d 253, 260 (Okla. 2013).

[271] Planned Parenthood Cincinnati Region v. Strickland, 531 F.3d 406, 408 (6th Cir. 2008).

[272] Okla. Coal. for Reprod. Just. v. Cline, 441 P.3d 1145, 1158 (Okla. 2019); *see* Planned Parenthood Ariz., Inc. v. Humble, 753 F.3d 905, 914–15 (9th Cir. 2014) ("[T]he evidence-based [off-label] regimen has a clear advantage over the on-label regimen.") (citation and quotation marks omitted).

[273] In 2016, FDA found "no new safety concerns have arisen in recent years, and that the known serious risks occur rarely," and approved the previous off-label protocol, changing the drug's indication, labeling, and REMS, including increasing the gestational age limit from forty-nine to seventy days. Washington v. FDA, No. 1:23-CV-3026-TOR, 2023 U.S. Dist. LEXIS 61776, at *8–9 (E.D. Wash. Apr. 7, 2023). *See also* U.S. FOOD & DRUG ADMIN., HIGHLIGHTS OF PRESCRIBING INFORMATION FOR MIFEPREX

treatment they need.[274] "[A]n estimated twenty-one to fifty percent of all prescriptions are for off-label indications" and "[i]n some patient groups, this number may exceed eighty percent."[275] The importance and prevalence of off-label use in the practice of medicine provides a complicated backdrop against which some states seek to limit or ban the use of mifepristone off-label, despite such off-label use being widely accepted and viewed as the medical standard of care.[276]

2. Promotion of FDA-Approved Drugs

FDA interprets its regulations as prohibiting manufacturer advertising encouraging off-label use.[277] In fact, "[t]he FDA regime banning off-label drug advertising has been in place, essentially unchanged, for decades."[278] Thus, courts interpreting the FDCA generally hold that it "prohibits pharmaceutical companies from marketing drugs for off-label uses[.]"[279] But "[t]he FDCA and its accompanying regulations do not expressly prohibit the 'promotion' or 'marketing' of drugs for off-label use."[280] In other words, "[n]o federal statute or regulation imposes, in so many words, a direct ban on off-label promotion of drugs."[281]

As a result, FDA bases its prohibition of off-label advertising on the combined effect of a series of statutes and regulations. First, the FDCA prohibits the

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(MIFEPRISTONE) §§ 6.1–6.2 (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf; FDA, MIFEPREX REMS, *supra* note 135.

274 *See Promotion of Drugs and Medical Devices for Unapproved Uses: Hearing Before the Human Resources and Intergovernmental Relations Subcomm. of the House Comm. on Gov't Operations*, 102d Cong., at 103 (1991) (statement of George Lundberg, MD, editor of JAMA) (asserting that "[t]here are too many variations in clinical circumstances and too much time delay in regulations to allow the government to impede the physician's ability to practice . . . when it is medically appropriate").

275 Beck, *supra* note 31, at 25 (quoting George Horvath, *Off-Label Drug Risks: Toward a New FDA Regulatory Approach*, 29 ANNALS HEALTH L. 101 (2020)).

276 Okla. Coal. for Reprod. Just. v. Cline, 441 P.3d at 1160; Planned Parenthood of the Heartland, Inc. v. Iowa Bd. of Med., 865 N.W.2d 252, 266 (Iowa 2015); MKB Mgmt. Corp. v. Burdick, 855 N.W.2d 31, 58 (N.D. 2014); Planned Parenthood of Greater Texas Surgical Health Servs. v. Abbott, 734 F.3d 406, 416–17 (5th Cir. 2013).

277 21 C.F.R. § 202.1(e)(4)(i)(a) ("An advertisement for a prescription drug . . . shall not recommend or suggest any use that is not in the labeling accepted in such approved new-drug application or supplement.").

278 Rodney A. Smolla, *Off-Label Drug Advertising and the First Amendment*, 50 WAKE FOREST L. REV. 81, 90 (2015); *see* Hoffman v. Sterling Drug, Inc., 485 F.2d 132, 138 (3d Cir. 1973) (discussing 1955 FDA regulation that "provided for FDA approval of 'any proposed change in the conditions under which such drug is to be used'" (footnote omitted)).

279 Lawton, *ex rel*. United States v. Takeda Pharm. Co., 842 F.3d 125, 128 n.4 (1st Cir. 2016); *see* Painters & Allied Trades Dist. Council 82 Health Care Fund v. Forest Pharms., Inc., 915 F.3d 1, 5 (1st Cir. 2019) ("The FDCA creates both civil and criminal penalties for drug manufacturers that promote the use of approved drugs for unapproved uses (referred to here as 'off-label' uses"). (citations omitted)); Bober v. Glaxo Wellcome PLC, 246 F.3d 934, 939 n.3 (7th Cir. 2001) ("FDA prohibits drug companies from promoting off-label uses for medications they manufacture or market . . . ." (citation omitted)).

280 United States v. Caronia, 703 F.3d 149, 154 (2d Cir. 2012) (pointing out the absence of definitions for these terms); *accord* United States v. Facteau, No. 15-CR-10076-ADB, 2020 U.S. Dist. LEXIS 167169, at *2 (D. Mass. Sept. 14, 2020) (stating that "there is no statute that specifically prohibits off label marketing"); Otis-Wisher v. Fletcher Allen Health Care, Inc., 951 F. Supp. 2d 592, 600 n.3 (D. Vt. 2013) (off-label promotion allegation is not "sufficiently specific" to plead a crime), *aff'd*, 616 F. App'x 433 (2d Cir. 2015).

281 Smolla, *supra* note 278, at 82.

"misbrand[ing]" of drugs and devices.[282] Second, FDA-approved products are "misbranded" if the labeling does not contain "adequate directions for use."[283] Third, "adequate directions for use" are only included in the context of the products' "intended use."[284] Fourth, if the product is "offered and used" for an off-label purpose, that promotion can establish a different "intended use" that is missing the required "adequate directions for use."[285]

While physician off-label use is "acceptable, and sometimes essential,"[286] or even an essential aspect of the practice and evolution of medicine,[287] it is not ordinarily within FDA's realm of oversight.[288] Thus, it is within the states' police power to regulate the actual practice of medicine beyond the (critical) determination of what medical products have been deemed safe and effective for the indications submitted to FDA. Despite its prevalence and the recognition of its benefits, there are risks when using FDA-approved medical products off-label.[289] Such risks can be significant because "[o]ff-label uses have not been subjected to the information-forcing mechanisms imposed by the new drug application process."[290] This matters for two reasons: "[f]irst, the safety and effectiveness of off-label uses have not been evaluated by the . . . staff of the FDA's CDER [Center for Drug Evaluation and Research]. Second, the safety and effectiveness of some off-label uses cannot be evaluated by clinicians."[291]

C. State Authority to Regulate the Practice of Medicine

While the FDCA statutory scheme, backed by the Constitution's Supremacy Clause, puts the regulation of drugs firmly under federal authority, states have broad authority to dictate how individual physicians and healthcare providers practice and, in some cases, how they prescribe those medications. Pursuant to the Constitution's Tenth Amendment, "[t]he powers not delegated to the United States by the

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[282] 21 U.S.C. § 331(a).

[283] *Id.* § 352(f); *see* United States v. Regenerative Scis., LLC, 741 F.3d 1314, 1323–24 (D.C. Cir. 2014) (examining the relationship between misbranding and "adequate directions for use" within FDCA provisions).

[284] 21 C.F.R. §§ 201.5, 801.5. Accordingly, "it is unlawful for a manufacturer to introduce a drug into interstate commerce with an intent that it be used for an off-label purpose." Washington Legal Found. v. Henney, 202 F.3d 331, 332 (D.C. Cir. 2000).

[285] 21 C.F.R. §§ 201.128, 801.4 ("intended use" determined by the "objective intent" of the manufacturer, as evidenced by "labeling claims, advertising matter, or oral or written statements by such persons or their representatives").

[286] Richardson v. Miller, 44 S.W.3d 1, 13 (Tenn. App. 2000) (citations omitted).

[287] Caplinger v. Medtronic, Inc., 921 F. Supp. 2d 1206, 1218 n.3 (W.D. Okla. 2013) ("[O]ff-label use is not illegal or even disfavored under federal law but is an accepted and valuable part of the practice of medicine."); Kashani-Matts v. Medtronic, Inc., No. SACV 13-01161-CJC, 2013 U.S. Dist. LEXIS 169518, at *5 n.4 (C.D. Cal. Nov. 22, 2013) ("[O]ff-label use is not merely legitimate but important in the practice of medicine.").

[288] *See* 21 U.S.C. §§ 355-1(f)(6), 352(y) (discussing FDA regulation of off-label use through REMS).

[289] James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 71–72 & n.6 (1998) (discussing the off-label use of fen-phen).

[290] Horvath, *supra* note 275, at 112.

[291] *Id.*; *see also* Amarin Pharma, Inc. v. FDA, 119 F. Supp. 3d 196, 204–05 (S.D.N.Y. 2015) (discussing harmful off-label uses).

Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."[292] As early as 1889, the Supreme Court acknowledged state police power, wielded by state medical boards, to regulate the practice of medicine:

> Few professions require more careful preparation by one who seeks to enter it than that of medicine. . . . The physician must be able to detect readily the presence of disease and prescribe appropriate remedies . . . . [C]omparatively few can judge of the qualifications of learning and skill which he possesses. Reliance must be placed upon the assurance given by his license, issued by an authority competent to judge in that respect, that he possesses the requisite qualifications. Due consideration, therefore, for the protection of society may well induce the State to exclude from practice those who have not such a license, or who are found upon examination not to be fully qualified.[293]

In 1905, the Supreme Court reaffirmed states' "police power" to regulate public health through mandatory vaccination, and with it "the authority of a state to enact . . . 'health laws of every description.'"[294] Likewise, "States have a compelling interest in the practice of professions within their boundaries, and that as part of their power to protect the public health, safety, and other valid interests they have broad power to establish standards for licensing practitioners and regulating the practice of professions."[295] As a result, "[t]he right to practice medicine . . . is subject to the paramount police power of the state."[296] Put another way, "the line between state and federal jurisdiction relies on the distinction between medical practice, which is regulated by individual states, and medical products, which are regulated by the federal government."[297]

The legislative history of the FDCA also reflects this clear divide of power: regulation of the practice of medicine is left to the states, while approval of safe and effective drugs is the exclusive power of the federal government. As former FDA General Counsel Peter Barton Hutt said before Congress:

> There is no question that FDA is authorized to approve the safety and effectiveness for all drugs . . . . On the other hand, the legislative history of both [the 1938 Food, Drug, and Cosmetic Act and the 1962 amendments] flatly states that FDA is not authorized to regulate the

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[292] U.S. CONST. amend. X.

[293] Dent v. West Virginia, 129 U.S. 114, 122–23 (1889); *see* Barsky v. Bd. of Regents, 347 U.S. 442, 451 (1954) (stating that the states have a "legitimate concern for maintaining high standards of professional conduct").

[294] Jacobson v. Massachusetts, 197 U.S. 11, 25 (1905). *See* Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 159 (2004) ("Thus, states could adopt vaccination and quarantine laws designed to protect the public health, and they also could exercise the power to license health care professionals.") (citations omitted).

[295] Goldfarb v. Va. State Bar, 421 U.S. 773, 792 (1975).

[296] Comm'n on Med. Discipline v. Stillman, 435 A.2d 747, 755 (Md. 1981) (citation omitted). *See* People v. Rogers, 641 N.W.2d 595, 605 (Mich. App. 2001) ("It is well established that a state can legitimately impose broad regulations on the practice of medicine through its police powers to protect the health, safety, and welfare of its citizens.").

[297] Myrisha S. Lewis, *Innovating Federalism in the Life Sciences*, 92 TEMP. L. REV. 383, 391 (2020).

> practice of medicine by requiring that physicians do or do not use specific drugs only in specific ways.[298]

The FDCA also preserves state authority concerning prescription drugs. The 1962 amendments to the FDCA include an express (but uncodified) savings clause that state law is preempted when there is "a direct and positive conflict between" the FDCA and "State law."[299]

States often define "the practice of medicine" statutorily, particularly as to who may legally practice medicine[300] and instituting requirements for licensure.[301] In the absence of contrary federal law, such as a drug-specific REMS,[302] state authority to regulate the health and safety of its citizens pursuant to its police power is far-reaching: states may impose vaccination mandates to protect its citizens[303] even in the face of religious objections,[304] as recent COVID-19 litigation has underscored.[305] A state's police power further extends to regulation of learned professions such as doctors and lawyers.[306] Recently, some states have "disregard[ed] federal *nonapproval* decisions" by "adopt[ing] laws authorizing the medical use of marijuana notwithstanding its continued status as a Schedule I (illicit) drug under federal law" and despite FDA's failure to approve its use.[307] States cannot be required, against their will, to enforce such federal prohibitions.[308]

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[298] *Hearings Before the Subcomm. of the H. Comm. on Gov't Operations*, 92d Cong., Nov. 11, 1971, at 103 (U.S. Gov. Printing Off. 1972) (statement of then-FDA General Counsel, Peter Barton Hutt).

[299] Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962).

[300] Gostin, *supra* note 236; *see Rogers*, 641 N.W.2d at 606–07.

[301] *See, e.g.*, Lori B. Andrews, *The Shadow Health Care System: Regulation of Alternative Health Care Providers*, 32 HOUS. L. REV. 1273, 1298–1308 (1996).

[302] *See* 21 U.S.C. §§ 355-1(f)(6), 352(y) (discussing FDA regulation of off-label use through REMS). Another example of federal limits to state control over medical practice is the Controlled Substances Act of 1970, 21 U.S.C. §§ 801, *et seq.*, Pub. L. No. 91-513, 84 Stat. 1236 (1970).

[303] Employment Div. v. Smith, 494 U.S. 872, 888–89 (1990) (vaccination mandates not subject to strict scrutiny); Zucht v. King, 260 U.S. 174, 176 (1922) ("[I]t is within the police power of a state to provide for compulsory vaccination."); Jacobson v. Massachusetts, 197 U.S. 11, 27–28 (1905).

[304] "The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death." Prince v. Massachusetts, 321 U.S. 158, 166–67 (1944).

[305] *E.g.*, Doe v. San Diego Unified Sch. Dist., 19 F.4th 1173, 1179 (9th Cir. 2021), *cert. denied*, 142 S. Ct. 1099 (2022); We the Patriots USA, Inc. v. Hochul, 17 F.4th 266, 287 (2d Cir. 2021), *cert. denied*, 142 S. Ct. 2569 (2022); Doe v. Mills, 16 F.4th 20, 29–31 (1st Cir. 2021), *cert. denied*, 142 S. Ct. 1112 (2022); Dr. A. v. Hochul, 586 F. Supp. 3d 136, 145 (N.D.N.Y. 2022) (all rejecting religiously based objections to COVID-19 vaccination mandates).

[306] Sperry v. Florida *ex rel*. Florida Bar, 373 U.S. 379 (1963); People v. Rogers, 641 N.W.2d 595, 605 (Mich. App. 2001); *see generally* James N. Thompson & Lisa A. Robin, *State Medical Boards. Future Challenges for Regulation and Quality Enhancement of Medical Care*, 33 J. LEGAL MED. 93 (2012) (discussing history of state medical boards); Lewis, *supra* note 297, at 390. *See also* Washington v. Glucksberg, 521 U.S. 702 (1997) (Washington State's ban on physician-assisted suicide promoted an important and legitimate government interest and did not offend the Fourteenth Amendment.).

[307] *See* Noah, *supra* note 99, at 22 (footnotes omitted).

[308] *See* Murphy v. Nat'l Collegiate Athletic Ass'n, 138 U.S. 1461, 1479 (2018) (state power cannot constitutionally be "commandeered" to enforce federal prohibitions).

VI. PREEMPTION AND ABORTION-RELATED LITIGATION AFTER *DOBBS*

Implicit in state regulation of the practice of medicine within its borders is the general tenant that physicians licensed in one state cannot treat patients in other states.[309] During the COVID-19 pandemic, telehealth was encouraged to the point that, for many people, it became their primary source of medical care,[310] so legal issues surrounding extraterritorial medical and pharmacy practice will affect state attempts to block importation of FDA-approved abortion-related medications by state residents.[311] Indeed, Kentucky's recent first-in-the-nation proposal for non-resident pharmacist licensure[312] lends itself, whether intentionally or not, to state interference with interstate prescription writing associated with telehealth, both for on- and off-label drug uses.

Considering the boundaries of coexisting federal and state authority over the prescription and distribution of drugs like mifepristone becomes more complicated and uncertain since the Supreme Court's ruling in *Dobbs*. The distinction between on- and off-label use will likely be at the core of whether such use falls under federal or state authority, particularly with regard to medication abortion. While previous challenges to state medication abortion restrictions did not require federal preemption arguments, with the demise of federal constitutional protection specific to reproductive freedom, other Supremacy Clause-based sources of federal preclusion will inevitably play a leading role.

Preemption is FDA's backup defense for science-based standards and the ordinarily apolitical integrity of its principal mission: to determine whether drugs are safe and effective for their intended uses.[313] When FDA approves prescription medication as safe and effective for the specific intended use of medication abortion in certain doses and with a prescribed frequency, but a state attempts to curtail its healthcare professionals' ability to prescribe those drugs through its police power and without the constitutional shield of *Roe v. Wade*, where will the legal analysis (and conclusion) lead? Deeply embedded in the Constitution and evolving case law, the doctrine of preemption will be something tangible, and supported by prior precedent, on which courts and commentators can rely as they navigate medication abortion after *Dobbs*.

For example, current and future FDA approval of mifepristone as safe and effective when used in different protocols moves the needle closer to the realm of supreme

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[309] Some states offer limited licenses for interstate telehealth practice. *See, e.g.*, FED'N OF STATE MED. BDS., TELEMEDICINE POLICIES: BOARD-BY-BOARD OVERVIEW 1 (Mar. 2023), https://www.fsmb.org/siteassets/advocacy/key-issues/telemedicine_policies_by_state.pdf. General state regulation of telemedicine is beyond the scope of this Article.

[310] *E.g.*, Deborah Farringer, *A Telehealth Explosion: Using Lessons from the Pandemic to Shape the Future of Telehealth Regulation*, 9 TEX. A&M L. REV. 1, 45–46 (2021).

[311] *E.g.*, J. Kelly Barnes, *Telemedicine: A Conflict of Laws Problem Waiting to Happen—How Will Interstate and International Claims Be Decided?*, 28 HOUS. J. INT'L L. 491, 519–26 (2006).

[312] *See* 201 KY. ADMIN. REGS. 2:030 (2022).

[313] *See, e.g.*, Lewis, *supra* note 297, at 388 (discussing "political and social considerations" that undercut FDA's accountability). *See generally* Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 576–77 (2001) (discussing the events concerning FDA review of mifepristone and concluding that FDA's decision-making process may have been politically motivated).

federal authority. Where a state tries to prohibit a physician within its borders from prescribing the medication, consistent with an FDA-approved indication, or a pharmacist from filling that prescription, or a patient from taking it, a palpable conflict between state and federal law arguably arises—if FDA thought additional restrictions were necessary to the public health, it would have imposed them. Although the Supreme Court ruled in *Dobbs* that abortion is not protected by constitutional Due Process,[314] the doctrine of preemption remains untouched. "States have no power . . . to retard, impede, burden, or in any manner control the operations of the constitutional laws enacted by Congress to carry into execution the powers vested in the general government."[315] This includes the FDCA, which Congress enacted to create FDA and empower it to approve and regulate pharmaceutical products and their indications. Thus,

> one could argue that any state efforts to prohibit or restrict distribution of mifepristone would create an impermissible conflict with federal law [because it would] stand[] as an 'obstacle' to the achievement of federal purposes. . . . Although limitations on the types of physicians who are authorized to dispense the drug (*e.g.*, only those licensed to perform surgical abortions) might pass muster, it does not appear that states could entirely prohibit access to a method for terminating pregnancy approved by federal officials.[316]

What was mostly an academic question twenty years ago has now become very real.[317]

Preemption-based arguments likely avoid *Dobbs* because preemption arises from the Supremacy Clause, whereas *Dobbs* interpreted substantive due process under the Fourteenth Amendment.[318] It will be a slippery slope indeed if states begin banning FDA-approved products, such as mifepristone, when used as directed by their FDA-approved labels. Obtaining FDA approval can take many years and billions of dollars to generate and assemble the necessary data.[319] Only after FDA stamps its approval of safety and efficacy can the drug's manufacturer begin to recoup this investment. If states may simply ban whatever FDA-approved drugs, vaccines, or medical devices they disapprove of politically, scientific and medical innovation, particularly of drugs (or vaccines) that might generate political controversy, will suffer. However, such bans are precisely what Supreme Court precedent rejects, whether framed as "inevitabl[e] conflict," "logical[] contradict[ion]," or "stop-selling."[320] Thus, as long as

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[314] Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2284 (2022).

[315] McCulloch v. Maryland, 17 U.S. 316, 436 (1819).

[316] Noah, *supra* note 313, at 601–02.

[317] Patricia J. Zettler & Ameet Sarpatwari, *State Restrictions on Mifepristone Access—The Case for Federal Preemption*, 386 N. ENG. J. MED. 705, 707 (Feb. 2022).

[318] *Dobbs*, 142 S. Ct. at 2242.

[319] CONG. BUDGET OFF., RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 13–14, (Apr. 2021), https://www.cbo.gov/publication/57126.

[320] Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001); Lipschultz v. Charter Advanced Servs. (MN), LLC, 140 U.S. 6, 7 (2019) (concurring opinion); Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 488 (2013).

mifepristone remains FDA-approved,[321] "[a] strong argument exists that state laws restricting mifepristone access . . . are preempted and should be challenged in court."[322]

But where the indication at issue is off-label, the conflict analysis is weaker, and may be outweighed by state authority to regulate the practice of medicine:

> It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power. The state's discretion in that field extends naturally to the regulation of all professions concerned with health.[323]

The medical standard of care for mifepristone medication abortions is no longer off-label.[324] But to preserve reproductive freedom, similar efforts need to be undertaken with respect to other abortion-related off-label uses. As has recently become clear, "[t]he health of millions of women throughout the country could benefit . . . ."[325]

In the wake of the *Dobbs* decision, it appears inevitable that the FDCA, by virtue of its preemptive effect on state law, and FDA itself, given its authority to regulate the national drug market, will be drawn into the ongoing culture wars over reproductive freedom. Culture wars eventually end,[326] but until this one does, expect FDA preemption issues to become one of many political footballs in the onslaught of post-*Dobbs* litigation.

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[321] *See* All. for Hippocratic Med. v. FDA, 78 F.4th 210 (5th Cir. 2023).

[322] Zettler & Sarpatwari, *supra* note 317, at 707. *Cf.* Carrie N. Baker, *FDA Abortion Pill Policy May Preempt State Restrictions, Say Legal Scholars: 'We Need to Push the Boundaries and See What Sticks'*, MS. MAG. (June 2, 2022), https://msmagazine.com/2022/06/02/state-restrictions-abortion-pills-fda-mifepristone/.

[323] Barsky v. Bd. of Regents, 347 U.S. 442, 449 (1954); *see* L.W. v. Skrmetti, 73 F.4th 408, 418 (6th Cir. 2023) (finding it "well within a State's police power to ban off-label uses"); Planned Parenthood Cincinnati Region v. Strickland, 531 F.3d 406, 407 (6th Cir. 2008) ("[T]he practice of medicine . . . is the exclusive realm of individual states.").

[324] *See supra* notes 20–21 and accompanying text.

[325] Zettler & Sarpatwari, *supra* note 317, at 707.

[326] *See* U.S. CONST. amends. XIII (abolishing slavery); XXI (repealing prohibition); XXIV (abolition of poll tax).