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States May Restrict Abortion Drugs

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KEY TAKEAWAYS

A growing majority of abortions are now the result of drugs rather than surgery.

Federal law is presumed not to preempt the states' police powers, including regulation of the medical profession and restricting or prohibiting abortion.

FDA approval means that a prescription drug may be marketed, not that it must be marketed or that states may not require additional safety measures.

For more than 250 years, since long before independence, American law protected human beings in the womb by increasingly restricting abortion. Local legislatures began to do so in the early 18th century,[1] and under the common law, "abortion... was regarded as unlawful and could have very serious consequences at all stages" of pregnancy.[2] State legislatures began to pass pro-life laws in 1821,[3] and nearly every state had done so by 1859, less than a decade before ratification of the Fourteenth Amendment. That year, the American Medical Association called on state legislatures to prevent the "unwarrantable destruction of human life" by prohibiting abortion.[4]

By 1973, most states prohibited abortion except to save the mother's life, and a handful that had modified their laws during the previous decade allowed abortion only for narrow reasons or only in early pregnancy.[5] In *Roe v. Wade*, however, the Supreme Court of

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the United States held for the first time that the Due Process Clause of the Fourteenth Amendment protected a woman's right to decide "whether or not to terminate her pregnancy."[6] The Court's rules for implementing this right rendered unconstitutional the pro-life laws of all 50 states.

According to data from the Centers for Disease Control and Prevention,[7] the number of abortions performed annually in the United States increased by nearly 80 percent in the five years after *Roe v. Wade*. Despite the decision and the surge in abortions, however, states continued their legislative efforts to protect human beings before birth, and cases challenging pro-life laws continued to come before the Supreme Court. In *Planned Parenthood v. Casey,*[8] the Court in 1992 reaffirmed *Roe*'s "central holding" that a woman has a constitutional right "to choose to have an abortion before viability."[9] Three decades later in *Dobbs v. Jackson Women's Health Organization*, a case challenging a Mississippi ban on most abortions after 15 weeks of pregnancy, the Supreme Court overruled both *Roe* and *Casey*, holding that "the Constitution does not confer a right to abortion."[10] The "authority to regulate abortion," Justice Samuel Alito wrote for the majority, "must be returned to the people and their elected representatives."[11] With the Supreme Court's blockade lifted, legislatures are pursuing this goal in both traditional and new ways.

Under the Tenth Amendment, states have all powers that are not "delegated to the United States by the Constitution, nor prohibited by it to the States."[12] These state powers include what is often referred to as a general "police power" to provide for "[p]ublic safety, public health, morality, peace and quiet, [and] law and order."[13] Relevant to the subject of this *Legal Memorandum*, the states' police power also includes both regulating the medical profession by proscribing certain procedures or setting standards for performing them[14] and regulating, restricting, or prohibiting abortion. A pro-life law, the Supreme Court held in *Dobbs*, is constitutional "if there is a rational basis on which the legislature could have thought that it would serve legitimate state interests."[15]

Much has changed, however, in the decades since 1973. Not only is the annual number of abortions in the United States on the rise after a 35-year decline,[16] but a growing majority of those abortions result from drugs rather than surgery.[17] In fact, abortion advocates often refer approvingly to "self-managed abortion."[18] As a result, states seeking to protect human life before birth face a new challenge. While reserving broad powers to the states, the Constitution also provides that "the Laws of the United States which shall be made in Pursuance [of the Constitution]...shall be the supreme Law of the Land...any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."[19] This provision is the basis

for the legal doctrine of *federal preemption*, the principle that "federal law supersedes conflicting state laws."[20] The preemption issue is relevant today because the U.S. Food and Drug Administration (FDA) has concluded that mifepristone and misoprostol, the drugs used for abortion, are "safe and effective" under certain conditions and therefore may be marketed.

As of July 2022, 33 states allowed only physicians to prescribe abortion drugs,[21] and 19 of these states also required that abortion drugs be dispensed in person rather than delivered through the mail.[22] Two states prohibit chemical abortions directly: Texas at seven weeks and Indiana at 10 weeks. As the Congressional Research Service notes, "a state's ability to restrict or prohibit access to these drugs may solely depend on the interplay between state and federal law."[23]

Within hours of the Supreme Court's overruling of *Roe* and *Casey*, Attorney General Merrick Garland issued a statement disagreeing with the decision, asserting that "the FDA has approved the use of the medication Mifepristone. States may not ban Mifepristone *based on disagreement with the FDA's expert judgment about its safety and efficacy*."[24] His statement, however, suggested that states may restrict or even ban abortion drugs based on other justifications or authority.

This *Legal Memorandum* addresses whether FDA approval of abortion drugs preempts state laws restricting or prohibiting them. The context for examining this specific question includes a review of federal drug regulation in general, the development of abortion drugs, and basic preemption principles. This analysis will apply those principles to conclude that no real preemption conflict exists and that, exercising their traditional powers to regulate the medical profession and to restrict or prohibit abortion, states may also restrict or prohibit abortion drugs.

Federal Drug Regulation

Statutes. Both the statutes that provide the structure for federal drug regulation and the FDA regulations that implement them carry out the FDA's mission of "assuring Americans that the medicines they use do no harm and actually work—that they are, in other words, *safe and effective*."[25] To that end, federal law prohibits introducing a prescription drug lacking such FDA approval into interstate commerce at all.[26]

- The **Pure Food and Drug Act,** enacted in 1906,[27] prohibited the interstate commerce of "any article of food or drug which is adulterated or misbranded,"[28] but it did not require evidence of safety or effectiveness as a condition for marketing.[29]

- The **Federal Food Drug and Cosmetic Act (FFDCA),**[30] enacted in 1938, established the FDA and is the statutory foundation for its current operation. It required evidence of a drug's safety before it could be marketed.[31]

- The **Kefauver–Harris Drug Amendments,** enacted in 1962, added the requirement of demonstrated effectiveness.[32]

The FDA does not opine generally about a drug's relative safety or efficacy in the abstract. A "foundational principle" of the FDA is that "a drug may be approved only if an applicant establishes the product to be safe and effective for its proposed indication and under the proposed conditions of use"[33] so that it may enter interstate commerce. In other words, the FDA's conclusion regarding a drug's safety and effectiveness "sets a regulatory floor,"[34] a threshold standard of safety and effectiveness, for the specific purpose of allowing a particular drug to enter or remain on the market.

Application and Approval Process. The FFDCA places the burden on a drug's manufacturer to provide "substantial evidence" of safety and effectiveness "under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."[35] The process begins with filing an *investigational new drug application* with the FDA[36] that includes information on animal testing and a proposed design for a clinical study involving humans. If those clinical trials are successful, the manufacturer will submit a *new drug application*, which contains the clinical trial results as well as information about the manufacturing process and facilities, product description, and labeling.[37] When reviewing a new drug application, the FDA considers whether the drug is "safe and effective in its proposed use," the "proposed labeling...is appropriate," and the manufacturing process is adequate to maintain the drug's quality and purity.[38]

In the 1980s, the FDA began to develop additional, more targeted risk management programs that included specific restrictions on the use of particular drugs.[39] In 1992, the FDA issued regulations for this purpose, allowing restrictions on a drug's marketing and use such as limiting distribution to certain facilities or to physicians with specific training.[40] The FDA Amendments Act of 2007 then gave the agency statutory authority to determine whether, in addition to "routine risk minimization measures,"[41] a formal "risk evaluation and mitigation strategy [REMS] is necessary to ensure that the benefits of the drug outweigh the risks of the drug."[42] Drugs with additional safety restrictions imposed before 2007 were "deemed to have in effect an approved [REMS]" until an actual REMS was approved.[43]

The FDA website explains that a REMS is "a drug safety program that the [FDA] can require for certain medications with *serious safety concerns*.... While all medications have labeling that informs health care stakeholders about medication risks, only a few medications require a REMS."[44] These safety measures go "beyond FDA-approved professional labeling" and may result in approval of drugs "that otherwise may have been kept off the market due to safety risks."[45]

Abortion Drugs

Development of RU-486. In 1980, the pharmaceutical company Roussel Uclaf synthesized the drug mifepristone, which ends a pregnancy by blocking the hormone progesterone that is necessary for a fertilized egg to attach to the uterine wall. Adding part of the drug's serial number to the company's initials produced the familiar name RU-486. The FDA approved the drug for clinical trials in 1983, but six years later, Roussel Uclaf stopped providing the drug for abortion in the United States.[46] In June 1989, based on concerns about the drug's possible health risks and use without physician supervision, the FDA prohibited the importation of RU-486 for personal use by placing the drug on its import alert list.[47]

The Population Council, which had been granted the right to market RU-486 in the United States, submitted a new drug application to the FDA on March 18, 1996,[48] and the FDA's advisory committee concluded in July that "it is safe and effective as an abortifacient *when used under close medical supervision*."[49] The need for such close supervision was widely accepted. In a June 23, 2000, *Washington Post* op-ed, abortion advocate Judy Mann noted: "All parties seem to agree that providers need specific training in how to administer this drug, counsel patients on its use *and provide surgical backup in case there are complications or the drug fails to work*."[50]

Approval of Mifeprex. Three months later, the FDA approved RU-486 as Mifeprex, the trademark of manufacturer Danco Laboratories, as a method of abortion during the first seven weeks of pregnancy.[51] From the start, the FDA subjected Mifeprex to its more rigorous safety restrictions. It was, for example, one of only nine drugs requiring additional restrictions under the FDA's pre-2007 regulatory standards.[52] Although the FDA "only rarely...place[s] restrictions on how a drug can be used by doctors,"[53] it did so for Mifeprex.[54] It could not be obtained, for example, through a pharmacy but had to be dispensed "directly in a physician's office, and it must be administered in the presence of a health professional."[55]

After passage of the FDA Amendments Act, mifepristone was initially deemed to have an approved REMS in effect.[56] The FDA approved a formal REMS on June 8, 2011, affirming that additional restrictions were necessary "to ensure that the benefits of the drug outweigh the risks of serious complications." These restrictions included Elements to Assure Safe Use (ETASU),[57] which provided that prescribing physicians must be "specially certified" and that mifepristone may be dispensed "only in certain health care settings...by or under the supervision of a specifically certified prescriber."

The FDA also issued a Medication Guide outlining how a patient should take the abortion drug combination. After a physical exam, a patient takes mifepristone in her provider's office and two days later, if still pregnant, returns to the office to take misoprostol. Two weeks after this process begins, the patient must return for a "very important" follow-up visit to ensure that the "pregnancy has completely ended."[58]

The FDA has modified the 2011 Mifeprex REMS three times.

- **March 2016:** The agency extended Mifeprex use to the first 10 weeks of pregnancy, continued the requirement that the drug "be dispensed in person to patients" only in certain clinical settings, and removed the requirement that the patient take mifepristone in a physician's office.[59]

- **April 2019:** The FDA approved a generic version of Mifeprex, manufactured by GenBioPro,[60] kept the 2016 REMS terms, but converted it to a shared REMS applying to both brand and generic versions.[61]

- **December 2021:** It permitted Mifeprex to be dispensed by certified pharmacies.

The most recent REMS revision did not occur in a vacuum. In May 2020, the American College of Obstetricians and Gynecologists (ACOG), which already opposed the in-person dispensing requirement for mifepristone, sued the FDA to lift it in light of the expanding COVID-19 pandemic.[62] The FDA was taking steps to "allow patients to forego unnecessary in-person visits,"[63] and declining to do so for mifepristone, ACOG argued, violated the rights of privacy and equal protection that, according to ACOG, were protected by the Fifth Amendment.[64]

On July 13, 2020, the U.S. District Court for the District of Maryland granted a preliminary injunction against the in-person dispensing requirement for mifepristone.[65] The district[66] and appeals[67] courts denied the

request for a stay, and the Supreme Court first held the stay application in abeyance[68] before granting the injunction on January 12, 2021. Concurring in that result, Chief Justice John Roberts wrote that because of the deference courts owe to "politically accountable entities" with responsibility for public health, there was an insufficient basis "for the District Court to compel the FDA to alter the regimen for medical abortion."[69]

That decision, however, had already been overtaken by political events. The 2020 election replaced a pro-life Administration with one seeking to advance abortion rights, including by promoting the availability of abortion drugs. The Biden Administration accomplished this goal in two steps.

- In April 2021, the FDA announced that it would not enforce the in-person dispensing requirement because "a clinic visit solely for this purpose" may present "additional COVID-related risks to patients and healthcare personnel."[70]

- In December 2021, without any reference to the pandemic, the FDA formally modified the shared REMS for mifepristone by removing the in-person dispensing requirement.

In summary, the FDA's approval identifies the point at which a drug's benefits exceed its risks for intended use in a manner that justifies allowing it to enter interstate commerce. The FDA approved mifepristone in 2000 under significant restrictions, including in-person prescribing and dispensing by physicians and in-person use by patients. Those restrictions remained in effect under both regulatory and statutory risk management regimes and have been relaxed only in the past several years. Even then, the restrictions have most recently been relaxed under changed political circumstances, after judicial intervention, and only under COVID-19 pandemic conditions.

Preemption Basics

Preemption Principles. The Constitution's general rule that federal law supersedes conflicting state law does not identify the actual situations requiring federal preemption. Supreme Court precedents, however, offer several relevant guidelines.

1. "Congress has the power to preempt state law,"[71] and the "purpose of Congress is the ultimate touchstone" in preemption cases.[72]

2. "[F]ederal law should not be read to preempt state law 'unless that is the clear and manifest purpose of Congress.'"[73]

3. This general presumption against preemption is stronger when the "'historic police powers of the States',"[74] such as regulating the medical profession,[75] are involved.

4. As a result, "the presumption [is] that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause."[76]

5. Therefore, with *Roe v. Wade* overruled, the states may again exercise their traditional police power to restrict or prohibit abortion.[77]

The Constitution provides for both federalism and federal preemption, and these principles are necessary to keep them properly balanced. More specifically, these preemption principles help to avoid, as the Supreme Court has warned, "an overbroad view of an agency's power to pre-empt state law."[78] Such an overbroad view may be less tempting in cases of *express preemption*, when Congress has stated its preemptive purpose in the text of a statute, than it is in cases of *implied preemption*, where Congress's purpose must be inferred.[79]

Express Preemption. "There is no doubt that Congress may withdraw specified powers from the States by enacting a statute containing an express preemption provision."[80] The Employment Retirement Income Security Act (ERISA), for example, states that its requirements for employee benefits plans "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan."[81] The Federal Railroad Safety Act expressed Congress's purpose in a different way, allowing states to enact laws related to railroad safety until the federal government adopted regulations "covering" or "substantially subsuming" the subject matter of such laws.[82] Congress has also expressly prohibited state requirements that are "in addition to, or different from" federal requirements.[83]

The presumption against preemption is not generally relevant in cases of express preemption because Congress's purpose in this context is discerned "from a statute's text."[84] In these cases, the courts will "tak[e] Congress at its word" and "giv[e] its words their ordinary, fair meaning."[85]

Implied Preemption. Courts have recognized two ways by which federal law can preempt state law in the absence of such an express statutory instruction: field preemption and conflict preemption.

Field preemption can occur "when a pervasive scheme of federal regulation implicitly precludes supplementary state regulation."[86] This can be "a field in which the federal interest is so dominant that the federal system will be presumed to preclude enforcement of state laws on the same subject."[87] Such fields include nuclear safety, construction and maintenance of tanker vessels, and the sale of natural gas in interstate commerce.[88] In *Arizona v. United States*,[89] for example, the Supreme Court held that "the Federal Government has occupied the field of alien registration"[90] and that a federal statute requiring that "aliens carry proof of registration"[91] preempted an Arizona law that, in effect, "add[ed] a state-law penalty for conduct proscribed by federal law."[92]

In *Ray v. Atlantic Richfield Co.*,[93] the Supreme Court held that the federal Ports and Waterways Safety Act[94] preempted a Washington state law regulating navigation of oil tankers in Puget Sound, including the requirement that tankers have a local pilot on board. The Court acknowledged the "'assumption that the historic police powers of the States were not to be superseded...unless that was the clear and manifest purpose of Congress.'"[95] Supreme Court precedents had long established that the federal government has exclusive authority to regulate pilots on vessels engaged in trade along the west coast. The State of Washington eventually conceded that the state and federal laws were indeed in direct conflict.[96]

In *California v. Federal Energy Regulatory Commission*,[97] the Supreme Court held that the Federal Power Act (FPA) preempted California state regulation of minimum stream flow related to hydroelectric power plants. The FPA has a provision suggesting that it should not "be construed as affecting or...interfer[ing] with" state laws "relating to the control, appropriation, use, or distribution of water used in irrigation or for municipal or other uses."[98] In 1946, however, the Supreme Court interpreted this provision to apply only to uses "of the same nature as those relating to the use of water in irrigation or for municipal purposes."[99] Since California did not seek to regulate stream flow for such purposes, there remained the FPA's creation of "a highly complex and long-enduring regulatory regime"[100] in which "Congress clearly intended a broad federal role in the development and licensing of hydroelectric power."[101]

Conflict preemption can occur when "compliance with both federal and state regulations is a physical impossibility"[102] or when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[103] Just as conflict preemption derives by inference rather than from statutory text, identifying an "obstacle" requiring preemption is a more subjective exercise than assessing "impossibility." The preemption principles, while always important, are therefore especially so in this latter category.

The Supreme Court has upheld federal preemption where there was a direct conflict between federal and state laws that set different rules on the same specific subject. In *Viking River Cruises, Inc. v. Moriana*,[104] for example, the Supreme Court held that the Federal Arbitration Act, which allows parties to agree on claims that will be subject to arbitration, preempted a California law that effectively required arbitration for certain claims. The Court applied "ordinary pre-emption principles" in *Barnett Bank of Marion County, N.A. v. Nelson*[105] to conclude that a 1916 federal law allowing certain national banks to sell insurance in small towns preempted a 1974 Florida law prohibiting them from doing so.

Zogenix v. Patrick[106] directly addressed whether FDA approval of a drug preempts state regulation. In 2014, then-Massachusetts Governor Deval Patrick declared a public health emergency to address the burgeoning opioid epidemic. Acting under this declaration, the state health commissioner prohibited the prescribing and dispensing of Zohydro ER, a hydrocodone analgesic, until an alternative "abuse-resistant formulation" of Zohydro had been created, which would require the company to "return to the FDA and seek approval of a drug different from the one the FDA has already deemed safe."[107] The U.S. District Court concluded that this amounted to Massachusetts "countermand[ing] the FDA's determination" and "interpos[ing] its own conclusion about Zohydro ER's safety and effectiveness."[108] Its actions were, as Attorney General Garland put it after the *Dobbs* decision, "based on disagreement with the FDA's expert judgment about its safety and efficacy."[109]

In other words, the FDA said that Zohydro could be marketed because it met the FDA's standards for safety and effectiveness, while Massachusetts said that it could not marketed until it met not only a different standard, but also one that actually required production of a different drug. The court put the issue this way:

> *Wyeth* [*v. Levine*] assumed the availability of the drug at issue and analyzed whether stronger state labeling requirements obstructed the FDA's objectives. Here, the obstruction is clearer because the drug Massachusetts wants Zogenix to adopt—Zohydro ER with an "abuse-resistant formulation"—has not been approved by the FDA. To satisfy the Commonwealth, Zogenix would be required to return to the FDA and seek approval of a drug different from the one the FDA has already deemed safe.[110]

In *Wyeth v. Levine*,[111] a state court jury awarded damages to a plaintiff who alleged that a drug manufacturer had failed to warn of certain risks.

The manufacturer argued that the FDA's approval of the drug's labeling presented an "actual conflict" and that the suit should therefore be dismissed. The Vermont Supreme Court held that the jury's verdict did not conflict with the FDA's approval because that approval "create[s] a floor, not a ceiling, for state regulation."[112]

The conflict in *Wyeth* was over the FDA's specific substantive judgment regarding the actual content of the drug's labeling. In other words, it was a much more "direct and positive" conflict with the FDA than state laws that add to the bottom-line safety measures required for FDA approval of abortion drugs. Even with such a direct conflict, however, the U.S. Supreme Court rejected the manufacturer's implied preemption arguments and affirmed the Vermont Supreme Court. Writing for the majority, Justice John Paul Stevens emphasized as one of the "cornerstones of our pre-emption jurisprudence"[113] the presumption, noted above, that "the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."[114]

The Court not only agreed that FDA approval sets a regulatory floor for safety and effectiveness, but also rejected the idea that FDA approval sets a ceiling. In fact, Justice Stevens wrote, the FDA itself "cast federal labeling standards as a floor upon which States could build.... It further noted that, in establishing 'minimal standards' for drug labels, it did not intend to 'preclude the states from imposing additional labeling requirements."[115]

Application and Analysis

Informed by these principles, the question is whether it is the "clear and manifest purpose of Congress"[116] that FDA approval of abortion drugs preempt state laws restricting them. On the federal side of the equation, the answer begins with the FFDCA's text. "As it enlarged the FDA's powers... Congress took care to preserve state law."[117] The 1962 Kefauver–Harris Amendments, for example, added language requiring a "direct and positive conflict" to preempt a state law regarding drug labeling.[118] That preemption provision, however, applies only to medical devices, not to drugs.[119]

The Supreme Court emphasized this point in *Riegel v. Medtronic*.[120] "Congress," Justice Antonin Scalia wrote in his majority opinion, "could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices."[121] Basic canons of statutory construction counsel that when the legislature includes language in one provision, its exclusion of that language from another is intentional and purposeful.[122] Citing *Riegel*, the Court in *Wyeth*

characterized Congress's decision not to apply preemption language in the FFDCA to drugs as "powerful evidence that Congress did *not* intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."[123]

The suggestion of implied preemption fares no better than the absence of express preemption. Two factors are important at this point in the analysis.

First, as explained above, the general presumption against preemption is stronger in situations involving the states' police powers. As Professor Patricia Zettler writes, "state laws governing pregnancy termination drugs are generally medical practice laws, limiting how practitioners may prescribe the drug."[124] Medical practice laws fall squarely within the states' general police powers, including regulating[125] the practice of medicine,[126] that the Supreme Court has repeatedly held federal regulation is presumed not to preempt. The Supreme Court held more than a century ago that it was already "too well settled to require discussion at this day that the police power of the State extends to the regulation of certain trades and callings, particularly those which closely concern the public health. There is perhaps no profession more properly open to such regulation than that which embraces the practitioners of medicine."[127] That presumption stands unrebutted by any evidence that Congress intended the requirement of FDA approval for marketing prescription drugs to preempt the states' police powers.

Second, clarity about the federal and state actions shows that they are simply not in conflict. As explained in this *Legal Memorandum*, the FFDCA prohibits prescription drugs from entering interstate commerce without FDA approval. That approval sets a minimum standard of safety and effectiveness, the point at which the benefits outweigh the costs. The fact that an FDA-approved drug *may* be marketed, however, does not mean that it *must* be marketed or *may only* be marketed in the manner that the FDA has approved. In *Wyeth*, the Supreme Court expressly rejected the argument that the FFDCA "established both a floor and a ceiling for drug regulation."[128] As noted above, the Court held that, by establishing minimum standards for introduction into interstate commerce, "[the FDA] did not intend to 'preclude the states from imposing additional... requirements.'"[129]

In 2016, the FDA revised mifepristone's REMS so that it would no longer require in-person prescribing or dispensing in specific clinical settings. If FDA approval of abortion drugs preempted state laws, mifepristone's REMS would constitute the exclusive conditions under which it could be marketed. This would directly contradict the Supreme Court's holding in *Wyeth* that FDA approval need not be "the exclusive means of ensuring drug safety and

effectiveness."[130] Again, that approval "sets a regulatory floor,"[131] a threshold for a drug entering or remaining on the market, a foundation upon which states can exercise their reserved powers to ensure public safety and to regulate the medical profession.

A state law that allowed the marketing of abortion drugs that failed to meet the FDA's approval standard for safety and effectiveness would pose a clear conflict and require federal preemption. State laws that "impos[e] additional...requirements," however, do not. State laws that impose such requirements do not challenge the FDA's standard, or its conclusion, for allowing abortion drugs on the market. They simply set a higher safety standard—one that the FDA itself had long imposed—for those drugs.

In fact, the Supreme Court has explicitly acknowledged that the states' power to regulate the medical profession includes the very kinds of restrictions that states are imposing on abortion drugs today.[132] The "Constitution gives the States broad latitude to decide that particular [medical] functions may be performed only by licensed professionals, even if an objective assessment might suggest that those same tasks could be performed by others."[133] These are the very restrictions that states today are applying to abortion drugs. While the right to abortion created in *Roe* and maintained in *Casey* tilted the balance against the states, *Dobbs* tilts that balance back in their favor[134] by overruling those precedents.[135]

As noted, the FDA evaluates whether prescription drugs are safe and effective for their proposed use. In the case of abortion drugs, that proposed use is the termination of pregnancy and is focused exclusively on the pregnant woman. State restrictions on abortion drugs, however, not only set a safety standard regarding the mother that is above the FDA floor, but also seek to reduce the number of human beings killed by those drugs in the womb. Since *Dobbs*, that objective is wholly within the states' police power.

The California Court of Appeals has put it this way: "As far as the [FFDCA] is concerned, it would be more accurate to say that the act evidences, far from implied preemption, an instance of implied *non*preemption."[136] Other federal statutes go even further. It is a federal crime, for example, to use the U.S. mail, a common carrier, or an "interactive computer service" to convey or deliver in interstate commerce any "thing which is advertised in a manner calculated to lead another to use or apply it for producing abortion"[137] or that is "designed, adapted, or intended for producing abortion."[138]

Preemption Case Study: *GenBioPro v. Dobbs*. While, as noted above, federal courts have addressed FDA approval of medical devices and drugs unrelated to abortion, none has yet to rule on the preemption question addressed in this *Legal Memorandum*. However, in a case of first impression,

the manufacturer of generic mifepristone sued Mississippi[139] over its law restricting the abortion drug. The Women's Health Defense Act of 2013[140] seeks to "[p]rotect women from the dangerous and potentially deadly use of abortion-inducing drugs when administration of the drugs does not meet the standard of care" and to "[e]nsure that physicians meet the standard of care when giving, selling, dispensing, administering or otherwise providing or prescribing abortion-inducing drugs."[141] To that end, the law restricts who may prescribe and administer mifepristone and the circumstances in which they may do so. Like the laws in other states, Mississippi's restrictions in large part mirror those once imposed by the FDA itself.

GenBioPro contended that these state limitations conflict with the FDA's determination that mifepristone is safe and effective for purposes of entering interstate commerce. While GenBioPro relied heavily on *Zogenix v. Patrick*,[142] the state even in that case was not prohibited from regulating certain aspects of the drug's distribution. Mississippi argued that agreeing with the manufacturer would not only preempt this state law, but also effectively neutralize a state's constitutional authority to regulate the medical profession and to restrict abortion.[143] Overruling *Dobbs* expanded rather than cut back states' authority to do so, Mississippi argued, and Congress has never displaced their authority to regulate the distribution of medications. Significantly, on August 18, 2022, less than two months after the Supreme Court returned authority over abortion to the people and their elected representatives, GenBioPro filed a notice of voluntary dismissal of its lawsuit.

Conclusion

The Constitution reserves to the states the powers to protect public health, regulate the medical profession, and restrict abortion. At the same time, it provides that federal law supersedes conflicting state law. With abortions once again on the rise, and with a growing majority of them involving drugs rather than surgery, states are enacting laws to prohibit abortion drugs or restrict how they may be used. Since those abortion drugs are regulated by the FDA, the question is whether FDA approval of abortion drugs presents a conflict with state laws that only federal preemption can resolve. The answer is "no."

In order to keep federalism and federal supremacy in balance, the Supreme Court has recognized a general presumption against preemption that is especially strong when states' traditional powers, such as regulating the medical profession, are involved. Additionally, with *Roe v. Wade*

and *Planned Parenthood v. Casey* overruled, the states may once against exercise their authority to restrict or prohibit abortion. This means that Congress must have a "clear and manifest purpose" to preempt state laws in an area like this.

There exists no real conflict between FDA approval of abortion drugs and state laws restricting or prohibiting them. FDA approval of abortion drugs as safe and effective for their proposed use set a regulatory floor for allowing them to enter or remain in interstate commerce, but it did not set a ceiling or exclude any other safety considerations. State laws that, for example, require in-person prescription and dispensing of abortion drugs, which the FDA itself had long required, do not conflict with the FDA's approval. Rather, they exercise states' authority to regulate the medical profession, enhance public safety, and restrict abortion.

Both the Supreme Court and state courts examining the question have characterized Congress' purpose as, in effect, the opposite of preemption. It has not imposed a statutory preemption requirement for drugs as it has for medical devices. And federal law explicitly makes criminal using the U.S. mail, common carriers, or computers to obtain abortion drugs. These and other considerations made the plaintiff in one lawsuit calling for federal preemption of abortion drug restrictions voluntarily withdraw its complaint. States may indeed use their constitutional authority to restrict or prohibit abortion drugs.

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Endnotes

1. *See* Sarah Parshall Perry & Thomas Jipping, Dobbs v. Jackson Women's Health Organization: *An Opportunity to Correct a Grave Error*, Heritage Found. Legal Memorandum No. 293 (Nov. 17, 2021), at 3 (New York City ordinance requiring oath by midwives not to "administer any…thing" to produce a miscarriage or abortion).
2. Dobbs v. Jackson Women's Health Organization, 142 S.Ct. 2228, 2235 (2022).
3. Roe v. Wade, 410 U.S. 113, 138 (1973).
4. Perry & Jipping, *supra* note 1, at 4.
5. *Id*. at 5. In this latter group, Alaska, Hawaii, New York, and Washington "repealed penalties for abortions performed in early pregnancy by a licensed physician, subject to stated procedural and health requirements." Karen J. Lewis, Morton Rosenberg & Allison I. Porter, Cong. Res. Serv., Abortion: Judicial and Legislative Control 3 (1981).
6. *Roe*, 410 U.S. at 153. See also Planned Parenthood v. Casey, 505 U.S. 833, 846 (1992).
7. Centers for Disease Control and Prevention, Reproductive Health, Morbidity and Mortality Weekly Report, https://www.cdc.gov/reproductivehealth/data_stats/index.htm.
8. 505 U.S. at 833.
9. The Supreme Court created the term "viability," defining it to mean when "the fetus [is] potentially able to live outside the mother's womb, albeit with artificial aid." *Roe*, 410 U.S. at 160. Many factors obviously affect whether a particular child is viable, but the current general consensus places viability at approximately 24 weeks of pregnancy.
10. *Dobbs*. 142 S.Ct. at 2279.
11. *Id*.
12. U.S. Const. amend. X.
13. Berman v. Parker, 348 U.S. 26, 32 (1954).
14. See Gonzales v. Oregon, 546 U.S. 243, 270 (2006). Even in *Roe*, the Supreme Court acknowledged that "a State may properly assert important interests in safeguarding health, in maintaining medical standards, and in protecting potential life." 410 U.S. at 154.
15. *Dobbs*, 142 S.Ct. at 2284. In *Roe* and subsequent decisions, the Supreme Court recognized a variety of interests supporting pro-life laws, labeling them valid, legitimate, important, strong, and significant. These interests exist throughout pregnancy. *See*, *e.g.*, *Roe*, 410 U.S. at 162, 163; Planned Parenthood v. Danforth, 428 U.S. 52, 61 (1976); Beal v. Doe, 432 U.S. 438, 445–46 (1977); Maher v. Roe, 432 U.S. 464, 478 (1977); Harris v. McRae, 448 U.S. 297, 313, 324 (1980); *Casey*, 505 U.S. at 846 (1992); Akron v. Akron Center for Reproductive Health, 462 U.S. 416, 428 (1983).
16. Both the Centers for Disease Control and Prevention (CDC) and the Guttmacher Institute (GI), the two primary sources of abortion data, have documented this pattern. The CDC data come from reports by state health departments, https://www.cdc.gov/mmwr/volumes/70/ss/ss7009a1.htm#methods; the GI data come from surveys of abortion providers. Because of this difference in data collection methods, GI totals have averaged 30 percent higher than CDC totals since 1973.
17. Rachel K. Jones, Elizabeth Nash, Lauren Cross, Jesse Philbin, & Marielle Kirstein, *Medication Abortion Now Accounts for More Than Half of All US Abortions*, Guttmacher Institute, Feb. 2022, https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions. As of 2020, 54 percent of all abortions in the United States were achieved via "medication abortion" using the drug mifepristone. *Id.*
18. *See*, *e.g.*, Megan K. Donovan, *Self-Managed Medication Abortion: Expanding the Available Options for U.S. Abortion Care*, Guttmacher Policy Review, Oct. 17, 2018, https://www.guttmacher.org/gpr/2018/10/self-managed-medication-abortion-expanding-available-options-us-abortion-care; Roni Caryn Rabin, *Some Women "Self-Manage" Abortions as Access Recedes*, N.Y. Times, Aug. 7, 2022, https://www.nytimes.com/2022/08/07/health/abortion-self-managed-medication.html.
19. U.S. Const. art. VI, cl. 2.
20. Jay B. Sykes & Nicole Vanatko, Cong. Res. Serv., Federal Preemption: A Legal Primer 1 (2019). The Supreme Court has held that "state laws can be pre-empted by federal regulations as well as by federal statutes." Hillsborough County, Fla. v. Automated Medical Laboratories, Inc., 471 U.S. 707, 714 (1985).
21. *See* Jennifer A. Staman & Jon O. Shimabukuro, Cong. Res. Serv., Medication Abortion: A Changing Legal Landscape 2 (2022).
22. See Guttmacher Institute, *Medication Abortion*, Aug. 1, 2022, https://www.guttmacher.org/state-policy/explore/medication-abortion.
23. Staman & Shimabukuro, *supra* note 21, at 1. This Legal Memorandum does not address whether state constitutions or state supreme courts have created any obstacles to state pro-life laws.
24. U.S. Department of Justice, *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. (emphasis added).

25. Agata Dabrowska & Susan Thaul, Cong. Res. Serv., How FDA Approves Drugs and Regulates Their Safety and Effectiveness 2 (2018) (emphasis in original). *See also* Erin D. Williams, Cong. Res. Serv., Food and Drug Administration (FDA): Overview and Issues 1 (2009).
26. 21 U.S. §355(a).
27. Pub. L. No. 59-384, 34 Stat. 786 (1906), https://govtrackus.s3.amazonaws.com/legislink/pdf/stat/34/STATUTE-34-Pg768.pdf.
28. Under this statute, a drug "shall be deemed to be adulterated" if its "strength, quality, or purity" differs from either the United States Pharmacopeia/National Formulary compendium of drug information or "the professional standard or quality under which it is sold." A drug "shall also be deemed to be misbranded" if it is "an imitation of or offered for sale under the name of another article"; if the package does not contain required information; or if the label fails to bear a statement regarding the "quantity or proportion" of substances such as morphine, cocaine, heroin, chloroform, or cannabis.
29. See Dabrowska and Thaul, *supra* note 25, at 1.
30. 21 U.S.C. §§ 301–399i.
31. See Stephen Daily, *A Brief History of the FDA*, Cataract & Refractive Surgery Today, Oct. 2011, at 68.
32. *Id*.
33. Julie Dohm and Mingham Ji, *An Introduction to Risk Evaluation and Mitigation Strategies*, 104 Contraception 4 (2021), https://www.contraceptionjournal.org/action/showPdf?pii=S0010-7824%2821%2900134-7.
34. *Recent Guidance, Reproductive Rights—Medication Abortion—FDA Lifts In-Person Dispensing Requirement for Mifepristone Abortion Pill*, 135 Harv. L. Rev. 2235, 2241 (2022).
35. 21 U.S.C. § 355(d). Substantial evidence consists of "adequate and well-controlled investigations...on the basis of which it could fairly and responsibly be concluded...that the drug will have the effect it purports or is represented to have." *Id*.
36. See Dabrowska and Thaul, *supra* note 25, at 4–5.
37. *Id*. at 5–6. A full New Drug Application contains "full reports of investigations of safety and effectiveness" that are conducted "by or for the applicant," and an Abbreviated New Drug Application includes information derived at least in part from "studies not conducted by or for the applicant...(e.g., published literature, FDA's findings of safety and/or effectiveness for a listed drug)." *Id*. at 6.
38. *Id*. at 6.
39. *See* Agata Dabrowska, Cong. Res. Serv., FDA Risk Evaluation and Mitigation Strategies (REMS): Description and Effect on Generic Drug Development 3 (2018).
40. See Dohm and Ji, *supra* note 33.
41. Dabrowska, *supra* note 39, at 1.
42. 21 U.S.C. § 355-1. See Dabrowska and Thaul, *supra* note 25, at 20–21; Dabrowska, *supra* note 39, at 4–5.
43. Identification of Drug and Biological Products, 73 Fed. Reg. 16313 (Mar. 27, 2008).
44. U.S. Food & Drug Administration, Risk Evaluation and Mitigation Strategies/REMS, https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems (emphasis added).
45. Dabrowska, *supra* note 39, at 2.
46. See Judith A. Johnson, Cong. Res. Serv., Abortion: Termination of Early Pregnancy with RU-486 (Mifepristone) at 2 (2001).
47. *Id*. *See also* Melanie Israel, *Chemical Abortion: A Review*, Heritage Found. Backgrounder No. 3603 (Mar. 26, 2021), at 4.
48. Government Accountability Office, Approval and Oversight of the Drug Mifeprex 15 (2008).
49. Johnson, *supra* note 46, at 5 (emphasis added).
50. Judy Mann, *We Need the Abortion Pill Now*, Wash. Post, June 23, 2000, at C9 (emphasis added), https://www.washingtonpost.com/archive/lifestyle/2000/06/23/we-need-the-abortion-pill-now/d5190008-9de6-4d77-acd5-71af382e8b73/.
51. Johnson, *supra* note 46, at 9.
52. Government Accountability Office, *supra* note 48, at 44.
53. Johnson, *supra* note 46, at 8.
54. *See* Government Accountability Office, *supra* note 48, at 5–6.
55. *Id*. at 45.
56. Identification of Drug and Biological Products, *supra* note 43. See also Israel, *supra* note 47, at 8.
57. U.S. Food and Drug Admin., Risk Evaluation and Mitigation Strategy (REMS), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2011-06-08_Full.pdf.
58. *Id*.
59. Dohm and Ji, *supra* note 33, at 6; Israel, *supra* note 47, at 9.

60. *See* U.S. Food and Drug Administration, Questions and Answers on Mifeprex, Dec. 16, 2021, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex.
61. Dohm and Ji, *supra* note 33, at 6.
62. ACOG v. U.S. FDA, 506 F.Supp.3d 328 (D.Md. 2020).
63. Dohm and Ji, *supra* note 33, at 2.
64. *Id*. at 38.
65. ACOG v. U.S. FDA, 506 F.Supp.3d 328 (D.Md. 2020).
66. *Id*.
67. ACOG v. State of Indiana and US FDA, 2021 WL 3276054 (7th Cir. 2021).
68. FDA v. ACOG, 141 S.Ct. 578 (2021).
69. *Id*. (Roberts, C.J., concurring).
70. Letter from Janet Woodcock, MD, to Maureen G. Phipps, MD, and William Gorbman, MD (Apr. 12, 2021), https://prochoice.org/wp-content/uploads/FDA-Acting-Commissioner-Letter-to-ACOG-April-12-2021.pdf.
71. Arizona v. United States, 567 U.S. 387, 399 (2012).
72. Retail Clerks v. Schermerhorn, 375 U.S. 96 (1963); Medtronic. Inc. v. Lohr, 518 U.S. 470, 485 (1996); Wyeth v. Levine, 555 U.S. 555, 565 (2009).
73. Sykes and Vanatko, *supra* note 20, at 3, quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947). See also State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645,654 (1995) (it is a rebuttable presumption that "Congress does not intend to supplant state law.").
74. Lorillard Tobacco v. Reilly, 533 U.S. 525, 542 (2001), quoting California Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc., 519 U.S. 316, 325 (1997). See also *Medtronic*, 518 U.S. at 475; Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, 7840 (1985) ("We also must presume that Congress did not intend to pre-empt areas of traditional state regulation."); Arizona v. United States, 567 U.S. 387, 400 (2012) ("courts should assume that 'the historic police powers of the States' are not superseded 'unless that was the clear and manifest purpose of Congress.'").
75. See Gonzales v. Oregon, 546 U.S. 243, 270 (2006).
76. *Hillsborough County*, 471 U.S. at 715.
77. In *Dobbs*, the Supreme Court held that these measures will be constitutional ""if there is a rational basis on which the legislature could have thought that it would serve legitimate state interests." 142 S.Ct. at 2284.
78. Wyeth v. Levine, 555 U.S. 555, 573 (2009).
79. See Crosby v. National Foreign Trade Council, 530 U.S. 363, 372-73 (2000).
80. *Arizona*, 567 U.S. at 399.
81. 29 U.S.C. § 1144(a). The Airline Deregulation Act similarly prohibits from enacting laws "relating to a price, route, or service of an air carrier." 49 U.S.C. § 41713(b)(1).
82. *See* CSX Transportation, Inc. v. Easterwood, 507 U.S. 658, 664 (2013).
83. *See*, *e.g.*, 7 U.S.C. §136v(b) (states "shall not impose or continue in effect any requirements for labeling and packaging [pesticides] *in addition to or different from* those required under this subchapter.") (emphasis added); *id*. at § 467 (e) ("Marking, labeling, packaging, or ingredient requirements… *in addition to, or different than*, those made under this subchapter may not be imposed by any State") (emphasis added); 21 U.S.C. § 360k(a) ("[N]o state…may establish or continue in effect with respect to a device intended for human use any requirement…which is *different from, or in addition to*, any requirement applicable under this chapter") (emphasis added).
84. *Medtronic*, 518 U.S. at 486.
85. Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 293 (2012). *See also* Puerto Rico v. Franklin California Tax-Free Trust, 579 U.S. 115 (2016).
86. Sykes and Vanatko, *supra* note 20, at 17. *See*, *e.g.*, Pennsylvania R. Co. v. Public Service Comm'n, 250 U.S. 566, 569 (1919); Cloverleaf Butter Co. v. Patterson, 315 U.S. 148, 173 (1942); *Ray*, 435 U.S. at 157–58; *Hillsborough County*, 471 U.S.at 713.
87. Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947). *See also* Gade v. National Solid Waste Mgmt. Ass'n, 505 U.S. 88, 98 (1992).
88. *See* Sykes and Vanatko, *supra* note 20, at 18. *See*, *e.g.*, Arizona v. United States, 567 U.S. 387, 394–95, 396 (2012) (federal government's "broad, undoubted power over the subject of immigration and the status of aliens…for the entire Nation" is "extensive and complex.").
89. *Arizona,* 567 U.S. at 387.
90. *Id*. at 401.
91. *Id*.
92. *Id*. at 400.

93. 435 U.S. 151 (1978).
94. 33 U.S.C. § 1221.
95. *Ray*, 435 U.S. at 157, quoting *Rice*, 331 U.S. at 230.
96. *See also* United States v. Locke, 529 U.S. 89 (2000) (applying *Ray* to same conclusion).
97. California v. Federal Energy Regulatory Commission, 495 U.S. 490 (1990).
98. 16 U.S.C. § 821.
99. First Iowa Hydro-Electric Cooperative v. FPC, 328 U.S. 152, 176 (1946).
100. *California*, 495 U.S. at 501.
101. *Id*. at 496.
102. Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132,142–43 (1963). See also Sykes and Vanatko, *supra* note 20, at 23–24; *Crosby*, 530 U.S. at 372.
103. Sykes and Vanatko, *supra* note 20, at 24, quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941). *See also* Chamber of Commerce v. Whiting, 563 U.S. 582, 607 (2011) ("Implied preemption does not justify a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives; such an endeavor 'would undercut the principle that it is Congress rather than the courts that preempts state law.'") (internal citations omitted).
104. 142 S.Ct. 1906 (2022).
105. *Barnett Bank*, 517 U.S. at 25.
106. 2014 WL1454696 (D. Mass. 2014).
107. *Id*. at *2.
108. *Id*.
109. U.S. Department of Justice, *supra* note 24.
110. *Id*. (emphasis added).
111. 555 U.S. at 555.
112. Levine v. Wyeth, 183 Vt. 76, 84 (2006).
113. *Wyeth*, 555 U.S. at 565.
114. *Id*. (internal citations omitted).
115. *Id*. at 577. The *Wyeth* Court expressly rejected Wyeth's claim that the "FDCA established both a floor and a ceiling for drug regulation: Once the FDA has approved a drug's label, a state-law verdict may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered the stronger warning at issue." *Id*. at 574.
116. *Supra* note 74.
117. *Wyeth*, 555 U.S. at 567.
118. *Id*.
119. 21 U.S.C. § 360k(a).
120. Riegel v. Medtronic, Inc., 522 U.S. 312, 315 (2008).
121. *Id.* at 327.
122. Legal information Institute, Statutory Construction, https://www.law.cornell.edu/wex/statutory_construction#:~:text=Statutory%20construction%20is%20the%20process,also%20known%20as%20statutory%20interpretation.
123. *Wyeth*, 555 U.S. at 575, quoting *Riegel*, 552 U.S. at 327. See also POM Wonderful LLC v. Coca-Cola Co., 134 S.Ct. 2228, 2238 (2014) ("By taking care to mandate express pre-emption of some state laws, Congress if anything indicated it did not intend the FDCA to preclude requirements arising from other sources.")
124. Patricia J. Zettler, *Pharmaceutical Federalism*, 92 Ind. L.J. 845, 869 n.160 (2017).
125. *See* Edward P. Richards, *The Police Power and the Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA-Qualified Managed Care Organizations*, 8 Annals of Health L. 201, 218 (1999).
126. The Supreme Court has asserted that the state police power includes overseeing medical practice and includes the prohibition of illegal drugs. *See*, *e.g.*, Whalen v. Roe, 429 U.S. 589, 597 (1977); Robinson v. California, 370 U.S. 660, 664 (1962).
127. Watson v. Maryland, 218 U.S. 173, 176 (1910).
128. *Wyeth*, 555 U.S. at 577.
129. *Id*. at 578.

130. *Id.* at 575, quoting *Riegel*, 552 U.S. at 327.
131. *Recent Guidance*, *supra* note 34, at 2241.
132. Some scholars have relied on the Supreme Court's most recent precedent on preemption of state "stop-selling" restrictions in Mutual Pharmaceutical Co., Inc. v. Bartlett, 570 U.S. 472 (2013) as a basis for arguing that a state may not ban mifepristone altogether. See James M. Beck, *Federal Preemption of State Attempts to Ban FDA-Approved Abortion Drugs After Dobbs*, Law and Device Blog, June 28, 2022, available at https://www.druganddevicelawblog.com/2022/06/federal-preemption-of-state-attempts-to-ban-fda-approved-abortion-drugs-after-dobbs.html. In *Mutual Pharmaceutical*, the court held that a state-law design-defect claim which turned on the adequacy of a generic drug's warning label was preempted by federal law. The state products liability law required increasing the drug's "usefulness" or "risk of danger" by redesign of its marketed drug. Either would require redesigning the drug—something that, due to its chemical composition, it was impossible to do. In addition, the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as its brand-name drug equivalent. Because redesign was impossible, Mutual Pharmaceutical could only lower the drug's "risk-utility" profile by strengthening its label warnings. This it could also not do, because the FDCA requires the same labeling requirements for a generic form of any drug as for the brand-name drug. Because it was impossible for Mutual Pharmaceutical to comply simultaneously with its federal-law duty not to alter its medication's label or composition and its state-law duty either to strengthen the warnings on sulindac's label or to change sulindac's composition, the state products liability law claim was preempted. In so holding, the court reversed the appellate court's rationale that Mutual Pharmaceutical could escape the impossibility of complying with both federal and state duties by choosing to stop selling its drug altogether, noting that an actor seeking to satisfy both obligations is not required to cease acting altogether. However, as discussed *infra*, the FDA approval of a drug is not a requirement that the drug must be manufactured or distributed within the state. The FDCA's requirements on abortifacient chemical composition and warning labels do not impact a state's power to ban that abortifacient as a valid exercise of its police power and in furtherance of its legitimate interest in protecting maternal health or unborn life.
133. *Casey*, 505 U.S. at 855.
134. The Constitution does not confer a right to abortion, but even for the enumerated rights that it does confer, such as those contained in the First and Second Amendments, there exist variations between the state and federal schemes. Americans choosing to exercise their Second Amendment right to keep and bear arms, for example, may have access to certain firearms sold in Utah and Texas that are not sold in New York or California (compare Tex. Penal Code § 46.05 (NFA firearms not restricted) and Utah Code Annotated § 76-10-509.5 (same) with Cal. Penal Code § 12220, 12020 (NFA Title II weapons prohibited without a license) and New York City Public Safety Code § 10-301 (NFA weapons prohibited for non-law-enforcement)). Additionally, while certain weapons are approved for sale by the federal government via the Bureau of Alcohol, Tobacco, Firearms and Explosives according to the National Gun Control Act, (18 U.S.C. Ch. 44), those same firearms may be further restricted within the states by way of state laws. While the First Amendment right to free speech and expression is unilaterally recognized as worthy of protection, limits on certain forms of speech also exist in the states and differ from state to state. Parade permit requirements in New York city, for example (see New York City Police Department Code ch. 19), are different than those in Salt Lake City, Utah (see Salt Lake County Municipal Code § 14.56.050(A)) (permit exemptions for protests and demonstrations protected by the First Amendment). Criminal defamation laws for prohibited speech exist in Florida (see Fla. Stat. 836.01)(libel punishable as a first-degree misdemeanor), but in its next-door neighbor, Georgia, defamation penalties are only civil in nature. If states may regulate the exercise of constitutional rights, their power to do so is even stronger for "rights" that were never in the Constitution to begin with.
135. At least one state supreme court has weighed in on the issue of abortifacients but provides little salience. In 2012, the Supreme Court of Oklahoma struck down a state law barring persons from using mifepristone in ways that contravened the FDA's protocol on dosage and use of the drug based on its impermissible infringement of a woman's constitutional "right" to an abortion. Oklahoma Coalition for Reproductive Justice v. Cline, 292 P.3d 27, 2012 OK 102 (2012). After *Dobbs*, abortion restrictions are to be evaluated under rational basis review—a standard generally more deferential to lawmakers. In applying that review standard, the *Cline* court might have reached a different conclusion and determined that a law restricting or prohibiting the use of mifepristone in ways that contravene FDA protocol is "rationally related" to the state's legitimate interests in maternal safety and protecting unborn life.
136. Consumer Justice Ctr. v. Olympian Labs, Inc., 121 Cal. Rptr. 2d 749, 755 (Cal. Ct. App. 2002) (emphasis in original).
137. 18 U.S.C. § 1461.
138. 18 U.S.C. § 1462(c).
139. GenBioPro, Inc. v. Dobbs, case 3:20-cv-652-HTW-LRA, S. Dist. Mississippi, Complaint filed October 9, 2020.
140. Codified as amended at Miss. Code Ann. §§ 41-41-101–117.
141. *Id.* § 41-41-103(2).
142. See *supra* note 106 and accompanying text.
143. Citing Gonzales v. Carhart, 550 U.S. 124, 145 (2007), for the proposition that the state maintains "its own regulatory interest in protecting the life of the fetus that may become a child" and Simopoulos v. Virginia, 462 U.S. 506, 519 (1983), for the proposition that a state has a "legitimate concern with the health of women who undergo abortions [and may]…properly assert important interests in safeguarding health [and] in maintaining medical standards."