Raising the Bar:

Defending Access to Abortion in New Jersey May 23, 2022, 12:30 – 2 p.m.

CLE Materials

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NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

DOBBS, STATE HEALTH OFFICER OF THE MISSISSIPPI DEPARTMENT OF HEALTH, ET AL. v. JACKSON WOMEN'S HEALTH ORGANIZATION ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

No. 19–1392. Argued December 1, 2021—Decided June 24, 2022

Mississippi's Gestational Age Act provides that "[e]xcept in a medical emergency or in the case of a severe fetal abnormality, a person shall not intentionally or knowingly perform . . . or induce an abortion of an unborn human being if the probable gestational age of the unborn human being has been determined to be greater than fifteen (15) weeks." Miss. Code Ann. §41–41–191. Respondents—Jackson Women's Health Organization, an abortion clinic, and one of its doctors—challenged the Act in Federal District Court, alleging that it violated this Court's precedents establishing a constitutional right to abortion, in particular Roe v. Wade, 410 U.S. 113, and Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833. The District Court granted summary judgment in favor of respondents and permanently enjoined enforcement of the Act, reasoning that Mississippi's 15-week restriction on abortion violates this Court's cases forbidding States to ban abortion pre-viability. The Fifth Circuit affirmed. Before this Court, petitioners defend the Act on the grounds that Roe and Casey were wrongly decided and that the Act is constitutional because it satisfies rational-basis review.

Held: The Constitution does not confer a right to abortion; *Roe* and *Casey* are overruled; and the authority to regulate abortion is returned to the people and their elected representatives. Pp. 8–79.

(a) The critical question is whether the Constitution, properly understood, confers a right to obtain an abortion. *Casey*'s controlling opinion skipped over that question and reaffirmed *Roe* solely on the basis of *stare decisis*. A proper application of *stare decisis*, however, requires an assessment of the strength of the grounds on which *Roe*

was based. The Court therefore turns to the question that the *Casey* plurality did not consider. Pp. 8–32.

- (1) First, the Court reviews the standard that the Court's cases have used to determine whether the Fourteenth Amendment's reference to "liberty" protects a particular right. The Constitution makes no express reference to a right to obtain an abortion, but several constitutional provisions have been offered as potential homes for an implicit constitutional right. Roe held that the abortion right is part of a right to privacy that springs from the First, Fourth, Fifth, Ninth, and Fourteenth Amendments. See 410 U.S., at 152-153. The Casey Court grounded its decision solely on the theory that the right to obtain an abortion is part of the "liberty" protected by the Fourteenth Amendment's Due Process Clause. Others have suggested that support can be found in the Fourteenth Amendment's Equal Protection Clause, but that theory is squarely foreclosed by the Court's precedents, which establish that a State's regulation of abortion is not a sex-based classification and is thus not subject to the heightened scrutiny that applies to such classifications. See Geduldig v. Aiello, 417 U.S. 484, 496, n. 20; Bray v. Alexandria Women's Health Clinic, 506 U.S. 263, 273-274. Rather, regulations and prohibitions of abortion are governed by the same standard of review as other health and safety measures. Pp. 9-11.
- (2) Next, the Court examines whether the right to obtain an abortion is rooted in the Nation's history and tradition and whether it is an essential component of "ordered liberty." The Court finds that the right to abortion is not deeply rooted in the Nation's history and tradition. The underlying theory on which *Casey* rested—that the Fourteenth Amendment's Due Process Clause provides substantive, as well as procedural, protection for "liberty"—has long been controversial.

The Court's decisions have held that the Due Process Clause protects two categories of substantive rights—those rights guaranteed by the first eight Amendments to the Constitution and those rights deemed fundamental that are not mentioned anywhere in the Constitution. In deciding whether a right falls into either of these categories, the question is whether the right is "deeply rooted in [our] history and tradition" and whether it is essential to this Nation's "scheme of ordered liberty." *Timbs* v. *Indiana*, 586 U. S. ___, __ (internal quotation marks omitted). The term "liberty" alone provides little guidance. Thus, historical inquiries are essential whenever the Court is asked to recognize a new component of the "liberty" interest protected by the Due Process Clause. In interpreting what is meant by "liberty," the Court must guard against the natural human tendency to confuse what the Fourteenth Amendment protects with the Court's own ardent views about the liberty that Americans should enjoy. For this reason,

the Court has been "reluctant" to recognize rights that are not mentioned in the Constitution. Collins v. Harker Heights, 503 U. S. 115, 125.

Guided by the history and tradition that map the essential components of the Nation's concept of ordered liberty, the Court finds the Fourteenth Amendment clearly does not protect the right to an abortion. Until the latter part of the 20th century, there was no support in American law for a constitutional right to obtain an abortion. No state constitutional provision had recognized such a right. Until a few years before Roe, no federal or state court had recognized such a right. Nor had any scholarly treatise. Indeed, abortion had long been a crime in every single State. At common law, abortion was criminal in at least some stages of pregnancy and was regarded as unlawful and could have very serious consequences at all stages. American law followed the common law until a wave of statutory restrictions in the 1800s expanded criminal liability for abortions. By the time the Fourteenth Amendment was adopted, three-quarters of the States had made abortion a crime at any stage of pregnancy. This consensus endured until the day *Roe* was decided. *Roe* either ignored or misstated this history, and Casey declined to reconsider Roe's faulty historical analysis.

Respondents' argument that this history does not matter flies in the face of the standard the Court has applied in determining whether an asserted right that is nowhere mentioned in the Constitution is nevertheless protected by the Fourteenth Amendment. The Solicitor General repeats Roe's claim that it is "doubtful . . . abortion was ever firmly established as a common-law crime even with respect to the destruction of a quick fetus," 410 U.S., at 136, but the great common-law authorities—Bracton, Coke, Hale, and Blackstone—all wrote that a postquickening abortion was a crime. Moreover, many authorities asserted that even a pre-quickening abortion was "unlawful" and that, as a result, an abortionist was guilty of murder if the woman died from the attempt. The Solicitor General suggests that history supports an abortion right because of the common law's failure to criminalize abortion before quickening, but the insistence on quickening was not universal, see Mills v. Commonwealth, 13 Pa. 631, 633; State v. Slagle, 83 N. C. 630, 632, and regardless, the fact that many States in the late 18th and early 19th century did not criminalize pre-quickening abortions does not mean that anyone thought the States lacked the authority to do so.

Instead of seriously pressing the argument that the abortion right itself has deep roots, supporters of *Roe* and *Casey* contend that the abortion right is an integral part of a broader entrenched right. *Roe* termed this a right to privacy, 410 U. S., at 154, and *Casey* described it as the freedom to make "intimate and personal choices" that are "central to personal dignity and autonomy," 505 U. S., at 851. Ordered

liberty sets limits and defines the boundary between competing interests. *Roe* and *Casey* each struck a particular balance between the interests of a woman who wants an abortion and the interests of what they termed "potential life." *Roe*, 410 U. S., at 150; *Casey*, 505 U. S., at 852. But the people of the various States may evaluate those interests differently. The Nation's historical understanding of ordered liberty does not prevent the people's elected representatives from deciding how abortion should be regulated. Pp. 11–30.

(3) Finally, the Court considers whether a right to obtain an abortion is part of a broader entrenched right that is supported by other precedents. The Court concludes the right to obtain an abortion cannot be justified as a component of such a right. Attempts to justify abortion through appeals to a broader right to autonomy and to define one's "concept of existence" prove too much. Casey, 505 U.S., at 851. Those criteria, at a high level of generality, could license fundamental rights to illicit drug use, prostitution, and the like. What sharply distinguishes the abortion right from the rights recognized in the cases on which Roe and Casey rely is something that both those decisions acknowledged: Abortion is different because it destroys what Roe termed "potential life" and what the law challenged in this case calls an "unborn human being." None of the other decisions cited by Roe and Casey involved the critical moral question posed by abortion. Accordingly, those cases do not support the right to obtain an abortion, and the Court's conclusion that the Constitution does not confer such a right does not undermine them in any way. Pp. 30–32.

(b) The doctrine of stare decisis does not counsel continued acceptance of Roe and Casey. Stare decisis plays an important role and protects the interests of those who have taken action in reliance on a past decision. It "reduces incentives for challenging settled precedents, saving parties and courts the expense of endless relitigation." Kimble v. Marvel Entertainment, LLC, 576 U.S. 446, 455. It "contributes to the actual and perceived integrity of the judicial process." Payne v. Tennessee, 501 U. S. 808, 827. And it restrains judicial hubris by respecting the judgment of those who grappled with important questions in the past. But stare decisis is not an inexorable command, Pearson v. Callahan, 555 U.S. 223, 233, and "is at its weakest when [the Court] interpret[s] the Constitution," Agostini v. Felton, 521 U.S. 203, 235. Some of the Court's most important constitutional decisions have overruled prior precedents. See, e.g., Brown v. Board of Education, 347 U.S. 483, 491 (overruling the infamous decision in Plessy v. Ferguson, 163 U.S. 537, and its progeny).

The Court's cases have identified factors that should be considered in deciding when a precedent should be overruled. *Janus* v. *State*, *County, and Municipal Employees*, 585 U. S. ___, ____. Five factors

discussed below weigh strongly in favor of overruling *Roe* and *Casey*. Pp. 39–66.

- (1) The nature of the Court's error. Like the infamous decision in Plessy v. Ferguson, Roe was also egregiously wrong and on a collision course with the Constitution from the day it was decided. Casey perpetuated its errors, calling both sides of the national controversy to resolve their debate, but in doing so, Casey necessarily declared a winning side. Those on the losing side—those who sought to advance the State's interest in fetal life—could no longer seek to persuade their elected representatives to adopt policies consistent with their views. The Court short-circuited the democratic process by closing it to the large number of Americans who disagreed with Roe. Pp. 43–45.
- (2) The quality of the reasoning. Without any grounding in the constitutional text, history, or precedent, Roe imposed on the entire country a detailed set of rules for pregnancy divided into trimesters much like those that one might expect to find in a statute or regulation. See 410 U. S., at 163–164. Roe's failure even to note the overwhelming consensus of state laws in effect in 1868 is striking, and what it said about the common law was simply wrong. Then, after surveying history, the opinion spent many paragraphs conducting the sort of factfinding that might be undertaken by a legislative committee, and did not explain why the sources on which it relied shed light on the meaning of the Constitution. As to precedent, citing a broad array of cases, the Court found support for a constitutional "right of personal privacy." Id., at 152. But Roe conflated the right to shield information from disclosure and the right to make and implement important personal decisions without governmental interference. See Whalen v. Roe, 429 U. S. 589, 599-600. None of these decisions involved what is distinctive about abortion: its effect on what Roe termed "potential life." When the Court summarized the basis for the scheme it imposed on the country, it asserted that its rules were "consistent with," among other things, "the relative weights of the respective interests involved" and "the demands of the profound problems of the present day." Roe, 410 U.S., at 165. These are precisely the sort of considerations that legislative bodies often take into account when they draw lines that accommodate competing interests. The scheme Roe produced looked like legislation, and the Court provided the sort of explanation that might be expected from a legislative body. An even more glaring deficiency was Roe's failure to justify the critical distinction it drew between pre- and post-viability abortions. See id., at 163. The arbitrary viability line, which Casey termed Roe's central rule, has not found much support among philosophers and ethicists who have attempted to justify a right to abortion. The most obvious problem with any such

argument is that viability has changed over time and is heavily dependent on factors—such as medical advances and the availability of quality medical care—that have nothing to do with the characteristics of a fetus.

When Casey revisited Roe almost 20 years later, it reaffirmed Roe's central holding, but pointedly refrained from endorsing most of its reasoning. The Court abandoned any reliance on a privacy right and instead grounded the abortion right entirely on the Fourteenth Amendment's Due Process Clause. 505 U. S., at 846. The controlling opinion criticized and rejected Roe's trimester scheme, 505 U. S., at 872, and substituted a new and obscure "undue burden" test. Casey, in short, either refused to reaffirm or rejected important aspects of Roe's analysis, failed to remedy glaring deficiencies in Roe's reasoning, endorsed what it termed Roe's central holding while suggesting that a majority might not have thought it was correct, provided no new support for the abortion right other than Roe's status as precedent, and imposed a new test with no firm grounding in constitutional text, history, or precedent. Pp. 45–56.

- (3) Workability. Deciding whether a precedent should be overruled depends in part on whether the rule it imposes is workable—that is, whether it can be understood and applied in a consistent and predictable manner. Casey's "undue burden" test has scored poorly on the workability scale. The Casey plurality tried to put meaning into the "undue burden" test by setting out three subsidiary rules, but these rules created their own problems. And the difficulty of applying Casey's new rules surfaced in that very case. Compare 505 U.S., at 881– 887, with id., at 920–922 (Stevens, J., concurring in part and dissenting in part). The experience of the Courts of Appeals provides further evidence that Casey's "line between" permissible and unconstitutional restrictions "has proved to be impossible to draw with precision." Janus, 585 U.S., at ___. Casey has generated a long list of Circuit conflicts. Continued adherence to Casey's unworkable "undue burden" test would undermine, not advance, the "evenhanded, predictable, and consistent development of legal principles." Payne, 501 U.S., at 827. Pp. 56-62.
- (4) Effect on other areas of law. Roe and Casey have led to the distortion of many important but unrelated legal doctrines, and that effect provides further support for overruling those decisions. See Ramos v. Louisiana, 590 U.S. ___, __ (KAVANAUGH, J., concurring in part). Pp. 62–63.
- (5) Reliance interests. Overruling Roe and Casey will not upend concrete reliance interests like those that develop in "cases involving property and contract rights." Payne, 501 U. S., at 828. In Casey, the controlling opinion conceded that traditional reliance interests were

not implicated because getting an abortion is generally "unplanned activity," and "reproductive planning could take virtually immediate account of any sudden restoration of state authority to ban abortions." 505 U.S., at 856. Instead, the opinion perceived a more intangible form of reliance, namely, that "people [had] organized intimate relationships and made choices that define their views of themselves and their places in society . . . in reliance on the availability of abortion in the event that contraception should fail" and that "[t]he ability of women to participate equally in the economic and social life of the Nation has been facilitated by their ability to control their reproductive lives." Ibid. The contending sides in this case make impassioned and conflicting arguments about the effects of the abortion right on the lives of women as well as the status of the fetus. The Casey plurality's speculative attempt to weigh the relative importance of the interests of the fetus and the mother represent a departure from the "original constitutional proposition" that "courts do not substitute their social and economic beliefs for the judgment of legislative bodies." Ferguson v. Skrupa, 372 U.S. 726, 729-730.

The Solicitor General suggests that overruling *Roe* and *Casey* would threaten the protection of other rights under the Due Process Clause. The Court emphasizes that this decision concerns the constitutional right to abortion and no other right. Nothing in this opinion should be understood to cast doubt on precedents that do not concern abortion. Pp. 63–66.

- (c) Casey identified another concern, namely, the danger that the public will perceive a decision overruling a controversial "watershed" decision, such as Roe, as influenced by political considerations or public opinion. 505 U. S., at 866–867. But the Court cannot allow its decisions to be affected by such extraneous concerns. A precedent of this Court is subject to the usual principles of stare decisis under which adherence to precedent is the norm but not an inexorable command. If the rule were otherwise, erroneous decisions like Plessy would still be the law. The Court's job is to interpret the law, apply longstanding principles of stare decisis, and decide this case accordingly. Pp. 66–69.
- (d) Under the Court's precedents, rational-basis review is the appropriate standard to apply when state abortion regulations undergo constitutional challenge. Given that procuring an abortion is not a fundamental constitutional right, it follows that the States may regulate abortion for legitimate reasons, and when such regulations are challenged under the Constitution, courts cannot "substitute their social and economic beliefs for the judgment of legislative bodies." *Ferguson*, 372 U. S., at 729–730. That applies even when the laws at issue concern matters of great social significance and moral substance. A law regulating abortion, like other health and welfare laws, is entitled to a

"strong presumption of validity." *Heller* v. *Doe*, 509 U. S. 312, 319. It must be sustained if there is a rational basis on which the legislature could have thought that it would serve legitimate state interests. *Id.*, at 320

Mississippi's Gestational Age Act is supported by the Mississippi Legislature's specific findings, which include the State's asserted interest in "protecting the life of the unborn." §2(b)(i). These legitimate interests provide a rational basis for the Gestational Age Act, and it follows that respondents' constitutional challenge must fail. Pp. 76–78

(e) Abortion presents a profound moral question. The Constitution does not prohibit the citizens of each State from regulating or prohibiting abortion. *Roe* and *Casey* arrogated that authority. The Court overrules those decisions and returns that authority to the people and their elected representatives. Pp. 78–79.

945 F. 3d 265, reversed and remanded.

ALITO, J., delivered the opinion of the Court, in which THOMAS, GORSUCH, KAVANAUGH, and BARRETT, JJ., joined. THOMAS, J., and KAVANAUGH, J., filed concurring opinions. ROBERTS, C. J., filed an opinion concurring in the judgment. BREYER, SOTOMAYOR, and KAGAN, JJ., filed a dissenting opinion.

NOTICE: This opinion is subject to formal revision before publication in the preliminary print of the United States Reports. Readers are requested to notify the Reporter of Decisions, Supreme Court of the United States, Washington, D. C. 20543, of any typographical or other formal errors, in order that corrections may be made before the preliminary print goes to press.

SUPREME COURT OF THE UNITED STATES

No. 19-1392

THOMAS E. DOBBS, STATE HEALTH OFFICER OF THE MISSISSIPPI DEPARTMENT OF HEALTH, ET AL., PETITIONERS v. JACKSON WOMEN'S HEALTH ORGANIZATION, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

[June 24, 2022]

JUSTICE ALITO delivered the opinion of the Court.

Abortion presents a profound moral issue on which Americans hold sharply conflicting views. Some believe fervently that a human person comes into being at conception and that abortion ends an innocent life. Others feel just as strongly that any regulation of abortion invades a woman's right to control her own body and prevents women from achieving full equality. Still others in a third group think that abortion should be allowed under some but not all circumstances, and those within this group hold a variety of views about the particular restrictions that should be imposed.

For the first 185 years after the adoption of the Constitution, each State was permitted to address this issue in accordance with the views of its citizens. Then, in 1973, this Court decided *Roe* v. *Wade*, 410 U. S. 113. Even though the Constitution makes no mention of abortion, the Court held that it confers a broad right to obtain one. It did not claim that American law or the common law had ever recognized

such a right, and its survey of history ranged from the constitutionally irrelevant (*e.g.*, its discussion of abortion in antiquity) to the plainly incorrect (*e.g.*, its assertion that abortion was probably never a crime under the common law). After cataloging a wealth of other information having no bearing on the meaning of the Constitution, the opinion concluded with a numbered set of rules much like those that might be found in a statute enacted by a legislature.

Under this scheme, each trimester of pregnancy was regulated differently, but the most critical line was drawn at roughly the end of the second trimester, which, at the time, corresponded to the point at which a fetus was thought to achieve "viability," i.e., the ability to survive outside the womb. Although the Court acknowledged that States had a legitimate interest in protecting "potential life," it found that this interest could not justify any restriction on previability abortions. The Court did not explain the basis for this line, and even abortion supporters have found it hard to defend Roe's reasoning. One prominent constitutional scholar wrote that he "would vote for a statute very much like the one the Court end[ed] up drafting" if he were "a legislator," but his assessment of Roe was memorable and brutal: Roe was "not constitutional law" at all and gave "almost no sense of an obligation to try to be."2

At the time of *Roe*, 30 States still prohibited abortion at all stages. In the years prior to that decision, about a third of the States had liberalized their laws, but *Roe* abruptly ended that political process. It imposed the same highly restrictive regime on the entire Nation, and it effectively struck down the abortion laws of every single State.³ As

¹Roe v. Wade, 410 U. S. 113, 163 (1973).

²J. Ely, The Wages of Crying Wolf: A Comment on *Roe* v. *Wade*, 82 Yale L. J. 920, 926, 947 (1973) (Ely) (emphasis deleted).

³L. Tribe, Foreword: Toward a Model of Roles in the Due Process of Life and Law, 87 Harv. L. Rev. 1, 2 (1973) (Tribe).

Justice Byron White aptly put it in his dissent, the decision represented the "exercise of raw judicial power," 410 U. S., at 222, and it sparked a national controversy that has embittered our political culture for a half century.⁴

Eventually, in *Planned Parenthood of Southeastern Pa.* v. Casey, 505 U. S. 833 (1992), the Court revisited Roe, but the Members of the Court split three ways. Two Justices expressed no desire to change *Roe* in any way.⁵ Four others wanted to overrule the decision in its entirety.⁶ And the three remaining Justices, who jointly signed the controlling opinion, took a third position. Their opinion did not endorse Roe's reasoning, and it even hinted that one or more of its authors might have "reservations" about whether the Constitution protects a right to abortion.⁸ But the opinion concluded that stare decisis, which calls for prior decisions to be followed in most instances, required adherence to what it called *Roe's* "central holding"—that a State may not constitutionally protect fetal life before "viability"—even if that holding was wrong.9 Anything less, the opinion claimed, would undermine respect for this Court and the rule of law.

Paradoxically, the judgment in *Casey* did a fair amount of overruling. Several important abortion decisions were

⁴See R. Ginsburg, Speaking in a Judicial Voice, 67 N. Y. U. L. Rev. 1185, 1208 (1992) ("*Roe*... halted a political process that was moving in a reform direction and thereby, I believed, prolonged divisiveness and deferred stable settlement of the issue").

⁵See 505 U. S., at 911 (Stevens, J., concurring in part and dissenting in part); *id.*, at 922 (Blackmun, J., concurring in part, concurring in judgment in part, and dissenting in part).

⁶See *id.*, at 944 (Rehnquist, C. J., concurring in judgment in part and dissenting in part); *id.*, at 979 (Scalia, J., concurring in judgment in part and dissenting in part).

⁷See *id.*, at 843 (joint opinion of O'Connor, Kennedy, and Souter, JJ.).

⁸ Id., at 853.

⁹ Id., at 860.

overruled *in toto*, and *Roe* itself was overruled in part.¹⁰ *Casey* threw out *Roe*'s trimester scheme and substituted a new rule of uncertain origin under which States were forbidden to adopt any regulation that imposed an "undue burden" on a woman's right to have an abortion.¹¹ The decision provided no clear guidance about the difference between a "due" and an "undue" burden. But the three Justices who authored the controlling opinion "call[ed] the contending sides of a national controversy to end their national division" by treating the Court's decision as the final settlement of the question of the constitutional right to abortion.¹²

As has become increasingly apparent in the intervening years, *Casey* did not achieve that goal. Americans continue to hold passionate and widely divergent views on abortion, and state legislatures have acted accordingly. Some have recently enacted laws allowing abortion, with few restrictions, at all stages of pregnancy. Others have tightly restricted abortion beginning well before viability. And in this case, 26 States have expressly asked this Court to overrule *Roe* and *Casey* and allow the States to regulate or prohibit pre-viability abortions.

Before us now is one such state law. The State of Mississippi asks us to uphold the constitutionality of a law that generally prohibits an abortion after the 15th week of pregnancy—several weeks before the point at which a fetus is now regarded as "viable" outside the womb. In defending this law, the State's primary argument is that we should reconsider and overrule *Roe* and *Casey* and once again allow each State to regulate abortion as its citizens wish. On the other side, respondents and the Solicitor General ask us to

¹⁰ Id., at 861, 870, 873 (overruling Akron v. Akron Center for Reproductive Health, Inc., 462 U. S. 416 (1983), and Thornburgh v. American College of Obstetricians and Gynecologists, 476 U. S. 747 (1986)).

^{11 505} U.S., at 874.

¹² Id., at 867.

reaffirm *Roe* and *Casey*, and they contend that the Mississippi law cannot stand if we do so. Allowing Mississippi to prohibit abortions after 15 weeks of pregnancy, they argue, "would be no different than overruling *Casey* and *Roe* entirely." Brief for Respondents 43. They contend that "no half-measures" are available and that we must either reaffirm or overrule *Roe* and *Casey*. Brief for Respondents 50.

We hold that *Roe* and *Casey* must be overruled. The Constitution makes no reference to abortion, and no such right is implicitly protected by any constitutional provision, including the one on which the defenders of *Roe* and *Casey* now chiefly rely—the Due Process Clause of the Fourteenth Amendment. That provision has been held to guarantee some rights that are not mentioned in the Constitution, but any such right must be "deeply rooted in this Nation's history and tradition" and "implicit in the concept of ordered liberty." *Washington* v. *Glucksberg*, 521 U. S. 702, 721 (1997) (internal quotation marks omitted).

The right to abortion does not fall within this category. Until the latter part of the 20th century, such a right was entirely unknown in American law. Indeed, when the Fourteenth Amendment was adopted, three quarters of the States made abortion a crime at all stages of pregnancy. The abortion right is also critically different from any other right that this Court has held to fall within the Fourteenth Amendment's protection of "liberty." *Roe*'s defenders characterize the abortion right as similar to the rights recognized in past decisions involving matters such as intimate sexual relations, contraception, and marriage, but abortion is fundamentally different, as both *Roe* and *Casey* acknowledged, because it destroys what those decisions called "fetal life" and what the law now before us describes as an "unborn human being." ¹³

Stare decisis, the doctrine on which Casey's controlling

¹³Miss. Code Ann. §41–41–191(4)(b) (2018).

opinion was based, does not compel unending adherence to *Roe*'s abuse of judicial authority. *Roe* was egregiously wrong from the start. Its reasoning was exceptionally weak, and the decision has had damaging consequences. And far from bringing about a national settlement of the abortion issue, *Roe* and *Casey* have enflamed debate and deepened division.

It is time to heed the Constitution and return the issue of abortion to the people's elected representatives. "The permissibility of abortion, and the limitations, upon it, are to be resolved like most important questions in our democracy: by citizens trying to persuade one another and then voting." *Casey*, 505 U. S., at 979 (Scalia, J., concurring in judgment in part and dissenting in part). That is what the Constitution and the rule of law demand.

Ι

The law at issue in this case, Mississippi's Gestational Age Act, see Miss. Code Ann. §41–41–191 (2018), contains this central provision: "Except in a medical emergency or in the case of a severe fetal abnormality, a person shall not intentionally or knowingly perform . . . or induce an abortion of an unborn human being if the probable gestational age of the unborn human being has been determined to be greater than fifteen (15) weeks." §4(b).¹⁴

To support this Act, the legislature made a series of factual findings. It began by noting that, at the time of enactment, only six countries besides the United States "permit[ted] nontherapeutic or elective abortion-on-demand after the twentieth week of gestation." §2(a). The legisla-

¹⁴The Act defines "gestational age" to be "the age of an unborn human being as calculated from the first day of the last menstrual period of the pregnant woman." §3(f).

¹⁵Those other six countries were Canada, China, the Netherlands,

ture then found that at 5 or 6 weeks' gestational age an "unborn human being's heart begins beating"; at 8 weeks the "unborn human being begins to move about in the womb"; at 9 weeks "all basic physiological functions are present"; at 10 weeks "vital organs begin to function," and "[h]air, fingernails, and toenails . . . begin to form"; at 11 weeks "an unborn human being's diaphragm is developing," and he or she may "move about freely in the womb"; and at 12 weeks the "unborn human being" has "taken on 'the human form' in all relevant respects." §2(b)(i) (quoting Gonzales v. Carhart, 550 U.S. 124, 160 (2007)). It found that most abortions after 15 weeks employ "dilation and evacuation procedures which involve the use of surgical instruments to crush and tear the unborn child," and it concluded that the "intentional commitment of such acts for nontherapeutic or elective reasons is a barbaric practice, dangerous for the maternal patient, and demeaning to the medical profession." $\S 2(b)(i)(8)$.

Respondents are an abortion clinic, Jackson Women's Health Organization, and one of its doctors. On the day the Gestational Age Act was enacted, respondents filed suit in Federal District Court against various Mississippi officials, alleging that the Act violated this Court's precedents establishing a constitutional right to abortion. The District

North Korea, Singapore, and Vietnam. See A. Baglini, Charlotte Lozier Institute, Gestational Limits on Abortion in the United States Compared to International Norms 6–7 (2014); M. Lee, Is the United States One of Seven Countries That "Allow Elective Abortions After 20 Weeks of Pregnancy?" Wash. Post (Oct. 8, 2017), www.washingtonpost.com/news/fact-checker/wp/2017/10/09/is-the-united-states-one-of-seven-countries-that-allow-elective-abortions-after-20-weeks-of-preganacy (stating that the claim made by the Mississippi Legislature and the Charlotte Lozier Institute was "backed by data"). A more recent compilation from the Center for Reproductive Rights indicates that Iceland and Guinea-Bissau are now also similarly permissive. See The World's Abortion Laws, Center for Reproductive Rights (Feb. 23, 2021), https://reproductiverights.org/maps/worlds-abortion-laws/.

Court granted summary judgment in favor of respondents and permanently enjoined enforcement of the Act, reasoning that "viability marks the earliest point at which the State's interest in fetal life is constitutionally adequate to justify a legislative ban on nontherapeutic abortions" and that 15 weeks' gestational age is "prior to viability." *Jackson Women's Health Org.* v. *Currier*, 349 F. Supp. 3d 536, 539–540 (SD Miss. 2019) (internal quotation marks omitted). The Fifth Circuit affirmed. 945 F. 3d 265 (2019).

We granted certiorari, 593 U. S. ___ (2021), to resolve the question whether "all pre-viability prohibitions on elective abortions are unconstitutional," Pet. for Cert. i. Petitioners' primary defense of the Mississippi Gestational Age Act is that *Roe* and *Casey* were wrongly decided and that "the Act is constitutional because it satisfies rational-basis review." Brief for Petitioners 49. Respondents answer that allowing Mississippi to ban pre-viability abortions "would be no different than overruling *Casey* and *Roe* entirely." Brief for Respondents 43. They tell us that "no half-measures" are available: We must either reaffirm or overrule *Roe* and *Casey*. Brief for Respondents 50.

II

We begin by considering the critical question whether the Constitution, properly understood, confers a right to obtain an abortion. Skipping over that question, the controlling opinion in *Casey* reaffirmed *Roe*'s "central holding" based solely on the doctrine of *stare decisis*, but as we will explain, proper application of *stare decisis* required an assessment of the strength of the grounds on which *Roe* was based. See *infra*, at 45–56.

We therefore turn to the question that the *Casey* plurality did not consider, and we address that question in three steps. First, we explain the standard that our cases have used in determining whether the Fourteenth Amendment's reference to "liberty" protects a particular right. Second,

we examine whether the right at issue in this case is rooted in our Nation's history and tradition and whether it is an essential component of what we have described as "ordered liberty." Finally, we consider whether a right to obtain an abortion is part of a broader entrenched right that is supported by other precedents.

> A 1

Constitutional analysis must begin with "the language of the instrument," *Gibbons* v. *Ogden*, 9 Wheat. 1, 186–189 (1824), which offers a "fixed standard" for ascertaining what our founding document means, 1 J. Story, Commentaries on the Constitution of the United States §399, p. 383 (1833). The Constitution makes no express reference to a right to obtain an abortion, and therefore those who claim that it protects such a right must show that the right is somehow implicit in the constitutional text.

Roe, however, was remarkably loose in its treatment of the constitutional text. It held that the abortion right, which is not mentioned in the Constitution, is part of a right to privacy, which is also not mentioned. See 410 U. S., at 152–153. And that privacy right, Roe observed, had been found to spring from no fewer than five different constitutional provisions—the First, Fourth, Fifth, Ninth, and Fourteenth Amendments. Id., at 152.

The Court's discussion left open at least three ways in which some combination of these provisions could protect the abortion right. One possibility was that the right was "founded . . . in the Ninth Amendment's reservation of rights to the people." *Id.*, at 153. Another was that the right was rooted in the First, Fourth, or Fifth Amendment, or in some combination of those provisions, and that this right had been "incorporated" into the Due Process Clause of the Fourteenth Amendment just as many other Bill of Rights provisions had by then been incorporated. *Ibid*; see

also *McDonald* v. *Chicago*, 561 U. S. 742, 763–766 (2010) (majority opinion) (discussing incorporation). And a third path was that the First, Fourth, and Fifth Amendments played no role and that the right was simply a component of the "liberty" protected by the Fourteenth Amendment's Due Process Clause. *Roe*, 410 U. S., at 153. *Roe* expressed the "feel[ing]" that the Fourteenth Amendment was the provision that did the work, but its message seemed to be that the abortion right could be found *somewhere* in the Constitution and that specifying its exact location was not of paramount importance. The *Casey* Court did not defend this unfocused analysis and instead grounded its decision solely on the theory that the right to obtain an abortion is part of the "liberty" protected by the Fourteenth Amendment's Due Process Clause.

We discuss this theory in depth below, but before doing so, we briefly address one additional constitutional provision that some of respondents' *amici* have now offered as yet another potential home for the abortion right: the Fourteenth Amendment's Equal Protection Clause. See Brief for United States as *Amicus Curiae* 24 (Brief for United States); see also Brief for Equal Protection Constitutional Law Scholars as *Amici Curiae*. Neither *Roe* nor *Casey* saw fit to invoke this theory, and it is squarely foreclosed by our precedents, which establish that a State's regulation of abortion is not a sex-based classification and is thus not subject to the "heightened scrutiny" that applies to such classifications. ¹⁷ The regulation of a medical procedure that

¹⁶The Court's words were as follows: "This right of privacy, whether it be founded in the Fourteenth Amendment's concept of personal liberty and restrictions upon state action, as we feel it is, or, as the District Court determined, in the Ninth Amendment's reservation of rights to the people, is broad enough to encompass a woman's decision whether or not to terminate her pregnancy." 410 U. S., at 153.

 $^{^{17}}$ See, e.g., Sessions v. Morales-Santana, 582 U. S. 47, ___ (2017) (slip op., at 8).

only one sex can undergo does not trigger heightened constitutional scrutiny unless the regulation is a "mere pretex[t] designed to effect an invidious discrimination against members of one sex or the other." *Geduldig* v. *Aiello*, 417 U. S. 484, 496, n. 20 (1974). And as the Court has stated, the "goal of preventing abortion" does not constitute "invidiously discriminatory animus" against women. *Bray* v. *Alexandria Women's Health Clinic*, 506 U. S. 263, 273–274 (1993) (internal quotation marks omitted). Accordingly, laws regulating or prohibiting abortion are not subject to heightened scrutiny. Rather, they are governed by the same standard of review as other health and safety measures. 18

With this new theory addressed, we turn to *Casey*'s bold assertion that the abortion right is an aspect of the "liberty" protected by the Due Process Clause of the Fourteenth Amendment. 505 U. S., at 846; Brief for Respondents 17; Brief for United States 21–22.

2

The underlying theory on which this argument rests—that the Fourteenth Amendment's Due Process Clause provides substantive, as well as procedural, protection for "liberty"—has long been controversial. But our decisions have held that the Due Process Clause protects two categories of substantive rights.

The first consists of rights guaranteed by the first eight Amendments. Those Amendments originally applied only to the Federal Government, *Barron ex rel. Tiernan* v. *Mayor of Baltimore*, 7 Pet. 243, 247–251 (1833) (opinion for the Court by Marshall, C. J.), but this Court has held that the Due Process Clause of the Fourteenth Amendment "incorporates" the great majority of those rights and thus makes them equally applicable to the States. See *McDonald*, 561

¹⁸We discuss this standard in Part VI of this opinion.

U. S., at 763–767, and nn. 12–13. The second category—which is the one in question here—comprises a select list of fundamental rights that are not mentioned anywhere in the Constitution.

In deciding whether a right falls into either of these categories, the Court has long asked whether the right is "deeply rooted in [our] history and tradition" and whether it is essential to our Nation's "scheme of ordered liberty." *Timbs* v. *Indiana*, 586 U. S. ____, ___ (2019) (slip op., at 3) (internal quotation marks omitted); *McDonald*, 561 U. S., at 764, 767 (internal quotation marks omitted); *Glucksberg*, 521 U. S., at 721 (internal quotation marks omitted). ¹⁹ And in conducting this inquiry, we have engaged in a careful analysis of the history of the right at issue.

Justice Ginsburg's opinion for the Court in *Timbs* is a recent example. In concluding that the Eighth Amendment's protection against excessive fines is "fundamental to our scheme of ordered liberty" and "deeply rooted in this Nation's history and tradition," 586 U. S., at ____ (slip op., at 7) (internal quotation marks omitted), her opinion traced the right back to Magna Carta, Blackstone's Commentaries, and 35 of the 37 state constitutions in effect at the ratification of the Fourteenth Amendment. 586 U. S., at _____ (slip op., at 3–7).

A similar inquiry was undertaken in *McDonald*, which held that the Fourteenth Amendment protects the right to keep and bear arms. The lead opinion surveyed the origins of the Second Amendment, the debates in Congress about

¹⁹ See also, e.g., Duncan v. Louisiana, 391 U. S. 145, 148 (1968) (asking whether "a right is among those 'fundamental principles of liberty and justice which lie at the base of our civil and political institutions'"); Palko v. Connecticut, 302 U. S. 319, 325 (1937) (requiring "a 'principle of justice so rooted in the traditions and conscience of our people as to be ranked as fundamental'" (quoting Snyder v. Massachusetts, 291 U. S. 97, 105 (1934))).

the adoption of the Fourteenth Amendment, the state constitutions in effect when that Amendment was ratified (at least 22 of the 37 States protected the right to keep and bear arms), federal laws enacted during the same period, and other relevant historical evidence. 561 U. S., at 767–777. Only then did the opinion conclude that "the Framers and ratifiers of the Fourteenth Amendment counted the right to keep and bear arms among those fundamental rights necessary to our system of ordered liberty." *Id.*, at 778; see also *id.*, at 822–850 (THOMAS, J., concurring in part and concurring in judgment) (surveying history and reaching the same result under the Fourteenth Amendment's Privileges or Immunities Clause).

Timbs and McDonald concerned the question whether the Fourteenth Amendment protects rights that are expressly set out in the Bill of Rights, and it would be anomalous if similar historical support were not required when a putative right is not mentioned anywhere in the Constitution. Thus, in Glucksberg, which held that the Due Process Clause does not confer a right to assisted suicide, the Court surveyed more than 700 years of "Anglo-American common law tradition," 521 U. S., at 711, and made clear that a fundamental right must be "objectively, deeply rooted in this Nation's history and tradition," id., at 720–721.

Historical inquiries of this nature are essential whenever we are asked to recognize a new component of the "liberty" protected by the Due Process Clause because the term "liberty" alone provides little guidance. "Liberty" is a capacious term. As Lincoln once said: "We all declare for Liberty; but in using the same word we do not all mean the same thing." In a well-known essay, Isaiah Berlin reported that "[h]istorians of ideas" had cataloged more than

 $^{^{20}\,\}mathrm{Address}$ at Sanitary Fair at Baltimore, Md. (Apr. 18, 1864), reprinted in 7 The Collected Works of Abraham Lincoln 301 (R. Basler ed. 1953).

200 different senses in which the term had been used.²¹

In interpreting what is meant by the Fourteenth Amendment's reference to "liberty," we must guard against the natural human tendency to confuse what that Amendment protects with our own ardent views about the liberty that Americans should enjoy. That is why the Court has long been "reluctant" to recognize rights that are not mentioned in the Constitution. Collins v. Harker Heights, 503 U.S. 115, 125 (1992). "Substantive due process has at times been a treacherous field for this Court," *Moore* v. *East Cleveland*, 431 U.S. 494, 503 (1977) (plurality opinion), and it has sometimes led the Court to usurp authority that the Constitution entrusts to the people's elected representatives. See Regents of Univ. of Mich. v. Ewing, 474 U. S. 214, 225-226 (1985). As the Court cautioned in Glucksberg, "[w]e must . . . exercise the utmost care whenever we are asked to break new ground in this field, lest the liberty protected by the Due Process Clause be subtly transformed into the policy preferences of the Members of this Court." 521 U.S., at 720 (internal quotation marks and citation omitted).

On occasion, when the Court has ignored the "[a]ppropriate limits" imposed by "'respect for the teachings of history," *Moore*, 431 U. S., at 503 (plurality opinion), it has fallen into the freewheeling judicial policymaking that characterized discredited decisions such as *Lochner* v. *New York*, 198 U. S. 45 (1905). The Court must not fall prey to such an unprincipled approach. Instead, guided by the history and tradition that map the essential components of our Nation's concept of ordered liberty, we must ask what the *Fourteenth Amendment* means by the term "liberty." When we engage in that inquiry in the present case, the clear answer is that the Fourteenth Amendment does not protect

²¹ Four Essays on Liberty 121 (1969).

the right to an abortion.²²

В

Until the latter part of the 20th century, there was no support in American law for a constitutional right to obtain an abortion. No state constitutional provision had recognized such a right. Until a few years before *Roe* was handed down, no federal or state court had recognized such a right. Nor had any scholarly treatise of which we are aware. And although law review articles are not reticent about advocating new rights, the earliest article proposing a constitutional right to abortion that has come to our attention was published only a few years before *Roe*.²³

²²That is true regardless of whether we look to the Amendment's Due Process Clause or its Privileges or Immunities Clause. Some scholars and Justices have maintained that the Privileges or Immunities Clause is the provision of the Fourteenth Amendment that guarantees substantive rights. See, e.g., McDonald v. Chicago, 561 U.S. 742, 813-850 (2010) (THOMAS, J., concurring in part and concurring in judgment); Duncan, 391 U.S., at 165–166 (Black, J., concurring); A. Amar, Bill of Rights: Creation and Reconstruction 163–180 (1998) (Amar); J. Ely, Democracy and Distrust 22-30 (1980); 2 W. Crosskey, Politics and the Constitution in the History of the United States 1089-1095 (1953). But even on that view, such a right would need to be rooted in the Nation's history and tradition. See Corfield v. Coryell, 6 F. Cas. 546, 551–552 (No. 3,230) (CC ED Pa. 1823) (describing unenumerated rights under the Privileges and Immunities Clause, Art. IV, §2, as those "fundamental" rights "which have, at all times, been enjoyed by the citizens of the several states"); Amar 176 (relying on *Corfield* to interpret the Privileges or Immunities Clause); cf. McDonald, 561 U.S., at 819–820, 832, 854 (opinion of THOMAS, J.) (reserving the question whether the Privileges or Immunities Clause protects "any rights besides those enumerated in the Constitution").

²³ See R. Lucas, Federal Constitutional Limitations on the Enforcement and Administration of State Abortion Statutes, 46 N. C. L. Rev. 730 (1968) (Lucas); see also D. Garrow, Liberty and Sexuality 334–335 (1994) (Garrow) (stating that Lucas was "undeniably the first person to fully

Not only was there no support for such a constitutional right until shortly before *Roe*, but abortion had long been a *crime* in every single State. At common law, abortion was criminal in at least some stages of pregnancy and was regarded as unlawful and could have very serious consequences at all stages. American law followed the common law until a wave of statutory restrictions in the 1800s expanded criminal liability for abortions. By the time of the adoption of the Fourteenth Amendment, three-quarters of the States had made abortion a crime at any stage of pregnancy, and the remaining States would soon follow.

Roe either ignored or misstated this history, and *Casey* declined to reconsider *Roe*'s faulty historical analysis. It is therefore important to set the record straight.

2 a

We begin with the common law, under which abortion was a crime at least after "quickening"—*i.e.*, the first felt movement of the fetus in the womb, which usually occurs between the 16th and 18th week of pregnancy.²⁴

articulate on paper" the argument that "a woman's right to choose abortion was a fundamental individual freedom protected by the U. S. Constitution's guarantee of personal liberty").

²⁴The exact meaning of "quickening" is subject to some debate. Compare Brief for Scholars of Jurisprudence as *Amici Curiae* 12–14, and n. 32 (emphasis deleted) ("'a quick child" meant simply a "live" child, and under the era's outdated knowledge of embryology, a fetus was thought to become "quick" at around the sixth week of pregnancy), with Brief for American Historical Association et al. as *Amici Curiae* 6, n. 2 ("quick" and "quickening" consistently meant "the woman's perception of fetal movement"). We need not wade into this debate. First, it suffices for present purposes to show that abortion was criminal by *at least* the 16th or 18th week of pregnancy. Second, as we will show, during the relevant period—*i.e.*, the period surrounding the enactment of the Fourteenth Amendment—the quickening distinction was abandoned as States criminalized abortion at all stages of pregnancy. See *infra*, at 21–

The "eminent common-law authorities (Blackstone, Coke, Hale, and the like)," *Kahler* v. *Kansas*, 589 U. S. ___, ___ (2020) (slip op., at 7), *all* describe abortion after quickening as criminal. Henry de Bracton's 13th-century treatise explained that if a person has "struck a pregnant woman, or has given her poison, whereby he has caused abortion, if the foetus be already formed and animated, and particularly if it be animated, he commits homicide." 2 De Legibus et Consuetudinibus Angliae 279 (T. Twiss ed. 1879); see also 1 Fleta, c. 23, reprinted in 72 Selden Soc. 60–61 (H. Richardson & G. Sayles eds. 1955) (13th-century treatise).²⁵

Sir Edward Coke's 17th-century treatise likewise asserted that abortion of a quick child was "murder" if the "childe be born alive" and a "great misprision" if the "childe dieth in her body." 3 Institutes of the Laws of England 50-51 (1644). ("Misprision" referred to "some heynous offence under the degree of felony." Id., at 139.) Two treatises by Sir Matthew Hale likewise described abortion of a quick child who died in the womb as a "great crime" and a "great misprision." Pleas of the Crown 53 (P. Glazebrook ed. 1972); 1 History of the Pleas of the Crown 433 (1736) (Hale). And writing near the time of the adoption of our Constitution, William Blackstone explained that abortion of a "quick" child was "by the ancient law homicide or manslaughter" (citing Bracton), and at least a very "heinous misdemeanor" (citing Coke). 1 Commentaries on the Laws of England 129-130 (7th ed. 1775) (Blackstone).

English cases dating all the way back to the 13th century corroborate the treatises' statements that abortion was a crime. See generally J. Dellapenna, Dispelling the Myths

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²⁵ Even before Bracton's time, English law imposed punishment for the killing of a fetus. See Leges Henrici Primi 222–223 (L. Downer ed. 1972) (imposing penalty for any abortion and treating a woman who aborted a "quick" child "as if she were a murderess").

of Abortion History 126, and n. 16, 134–142, 188–194, and nn. 84–86 (2006) (Dellapenna); J. Keown, Abortion, Doctors and the Law 3–12 (1988) (Keown). In 1732, for example, Eleanor Beare was convicted of "destroying the Foetus in the Womb" of another woman and "thereby causing her to miscarry." For that crime and another "misdemeanor," Beare was sentenced to two days in the pillory and three years' imprisonment.²⁷

Although a pre-quickening abortion was not itself considered homicide, it does not follow that abortion was *permissible* at common law—much less that abortion was a legal *right*. Cf. *Glucksberg*, 521 U. S., at 713 (removal of "common law's harsh sanctions did not represent an acceptance of suicide"). Quite to the contrary, in the 1732 case mentioned above, the judge said of the charge of abortion (with no mention of quickening) that he had "never met with a case so barbarous and unnatural." Similarly, an indictment from 1602, which did not distinguish between a prequickening and post-quickening abortion, described abortion as "pernicious" and "against the peace of our Lady the Queen, her crown and dignity." Keown 7 (discussing *R. v. Webb*, Calendar of Assize Records, Surrey Indictments 512 (1980)).

That the common law did not condone even prequickening abortions is confirmed by what one might call a proto-felony-murder rule. Hale and Blackstone explained a way in which a pre-quickening abortion could rise to the level of a homicide. Hale wrote that if a physician gave a woman "with child" a "potion" to cause an abortion, and the woman died, it was "murder" because the potion was given "unlawfully to destroy her child within her." 1 Hale 429–430 (emphasis added). As Blackstone explained, to be

²⁶2 Gentleman's Magazine 931 (Aug. 1732).

²⁷ Id., at 932.

 $^{^{28}}Ibid.$

"murder" a killing had to be done with "malice afore-thought, . . . either express or implied." 4 Blackstone 198 (emphasis deleted). In the case of an abortionist, Blackstone wrote, "the law will imply [malice]" for the same reason that it would imply malice if a person who intended to kill one person accidentally killed a different person:

"[I]f one shoots at A and misses *him*, but kills B, this is murder; because of the previous felonious intent, which the law transfers from one to the other. The same is the case, where one lays poison for A; and B, against whom the prisoner had no malicious intent, takes it, and it kills him; this is likewise murder. *So also*, if one gives *a woman with child* a medicine to procure abortion, and it operates so violently as to kill the woman, *this is murder* in the person who gave it." *Id.*, at 200–201 (emphasis added; footnote omitted).²⁹

Notably, Blackstone, like Hale, did not state that this proto-felony-murder rule required that the woman be "with quick child"—only that she be "with child." *Id.*, at 201. And it is revealing that Hale and Blackstone treated abortionists differently from *other* physicians or surgeons who caused the death of a patient "without any intent of doing [the patient] any bodily hurt." Hale 429; see 4 Blackstone 197. These other physicians—even if "unlicensed"—would not be "guilty of murder or manslaughter." Hale 429. But a physician performing an abortion would, precisely because his aim was an "unlawful" one.

In sum, although common-law authorities differed on the severity of punishment for abortions committed at different

²⁹Other treatises restated the same rule. See 1 W. Russell & C. Greaves, Crimes and Misdemeanors 540 (5th ed. 1845) ("So where a person gave medicine to a woman to procure an abortion, and where a person put skewers into the woman for the same purpose, by which in both cases the women were killed, these acts were clearly held to be murder" (footnotes omitted)); 1 E. East, Pleas of the Crown 230 (1803) (similar).

points in pregnancy, none endorsed the practice. Moreover, we are aware of no common-law case or authority, and the parties have not pointed to any, that remotely suggests a positive *right* to procure an abortion at any stage of pregnancy.

b

In this country, the historical record is similar. The "most important early American edition of Blackstone's Commentaries," District of Columbia v. Heller, 554 U.S. 570, 594 (2008), reported Blackstone's statement that abortion of a quick child was at least "a heinous misdemeanor," 2 St. George Tucker, Blackstone's Commentaries 129–130 (1803), and that edition also included Blackstone's discussion of the proto-felony-murder rule, 5 id., at 200–201. Manuals for justices of the peace printed in the Colonies in the 18th century typically restated the common-law rule on abortion, and some manuals repeated Hale's and Blackstone's statements that anyone who prescribed medication "unlawfully to destroy the child" would be guilty of murder if the woman died. See, e.g., J. Parker, Conductor Generalis 220 (1788); 2 R. Burn, Justice of the Peace, and Parish Officer 221–222 (7th ed. 1762) (English manual stating the same).30

³⁰ For manuals restating one or both rules, see J. Davis, Criminal Law 96, 102–103, 339 (1838); Conductor Generalis 194–195 (1801) (printed in Philadelphia); Conductor Generalis 194–195 (1794) (printed in Albany); Conductor Generalis 220 (1788) (printed in New York); Conductor Generalis 198 (1749) (printed in New York); G. Webb, Office and Authority of a Justice of Peace 232 (1736) (printed in Williamsburg); Conductor Generalis 161 (1722) (printed in Philadelphia); see also J. Conley, Doing It by the Book: Justice of the Peace Manuals and English Law in Eighteenth Century America, 6 J. Legal Hist. 257, 265, 267 (1985) (noting that these manuals were the justices' "primary source of legal reference" and of "practical value for a wider audience than the justices").

For cases stating the proto-felony-murder rule, see, e.g., Commonwealth v. Parker, 50 Mass. 263, 265 (1845); People v. Sessions, 58 Mich.

The few cases available from the early colonial period corroborate that abortion was a crime. See generally Dellapenna 215–228 (collecting cases). In Maryland in 1652, for example, an indictment charged that a man "Murtherously endeavoured to destroy or Murther the Child by him begotten in the Womb." *Proprietary* v. *Mitchell*, 10 Md. Archives 80, 183 (1652) (W. Browne ed. 1891). And by the 19th century, courts frequently explained that the common law made abortion of a quick child a crime. See, *e.g.*, *Smith* v. *Gaffard*, 31 Ala. 45, 51 (1857); *Smith* v. *State*, 33 Me. 48, 55 (1851); *State* v. *Cooper*, 22 N. J. L. 52, 52–55 (1849); *Commonwealth* v. *Parker*, 50 Mass. 263, 264–268 (1845).

C

The original ground for drawing a distinction between pre- and post-quickening abortions is not entirely clear, but some have attributed the rule to the difficulty of proving that a pre-quickening fetus was alive. At that time, there were no scientific methods for detecting pregnancy in its early stages,³¹ and thus, as one court put it in 1872: "[U]ntil the period of quickening there is no evidence of life; and whatever may be said of the feotus, the law has fixed upon this period of gestation as the time when the child is endowed with life" because "foetal movements are the first clearly marked and well defined evidences of life." Evans v. People, 49 N.Y. 86, 90 (emphasis added); Cooper, 22 N. J. L., at 56 ("In contemplation of law life commences at the moment of quickening, at that moment when the embryo gives the first physical proof of life, no matter when it first received it" (emphasis added)).

^{594, 595–596, 26} N. W. 291, 292–293 (1886); State v. Moore, 25 Iowa 128, 131–132 (1868); Smith v. State, 33 Me. 48, 54–55 (1851).

 $^{^{31}}$ See E. Rigby, A System of Midwifery 73 (1841) ("Under all circumstances, the diagnosis of pregnancy must ever be difficult and obscure during the early months"); see also id., at 74–80 (discussing rudimentary techniques for detecting early pregnancy); A. Taylor, A Manual of Medical Jurisprudence 418–421 (6th Am. ed. 1866) (same).

The Solicitor General offers a different explanation of the basis for the quickening rule, namely, that before quickening the common law did not regard a fetus "as having a 'separate and independent existence.'" Brief for United States 26 (quoting *Parker*, 50 Mass., at 266). But the case on which the Solicitor General relies for this proposition also suggested that the criminal law's quickening rule was out of step with the treatment of prenatal life in other areas of law, noting that "to many purposes, in reference to civil rights, an infant *in ventre sa mere* is regarded as a person in being." *Ibid.* (citing 1 Blackstone 129); see also *Evans*, 49 N. Y., at 89; *Mills* v. *Commonwealth*, 13 Pa. 631, 633 (1850); *Morrow* v. *Scott*, 7 Ga. 535, 537 (1849); *Hall* v. *Hancock*, 32 Mass. 255, 258 (1834); *Thellusson* v. *Woodford*, 4 Ves. 227, 321–322, 31 Eng. Rep. 117, 163 (1789).

At any rate, the original ground for the quickening rule is of little importance for present purposes because the rule was abandoned in the 19th century. During that period, treatise writers and commentators criticized the quickening distinction as "neither in accordance with the result of medical experience, nor with the principles of the common law." F. Wharton, Criminal Law §1220, p. 606 (rev. 4th ed. 1857) (footnotes omitted); see also J. Beck, Researches in Medicine and Medical Jurisprudence 26–28 (2d ed. 1835) (describing the quickening distinction as "absurd" and "injurious").³² In 1803, the British Parliament made abortion

³² See *Mitchell* v. *Commonwealth*, 78 Ky. 204, 209–210 (1879) (acknowledging the common-law rule but arguing that "the law should punish abortions and miscarriages, willfully produced, at any time during the period of gestation"); *Mills* v. *Commonwealth*, 13 Pa., 631, 633 (1850) (the quickening rule "never ought to have been the law anywhere"); J. Bishop, Commentaries on the Law of Statutory Crimes §744, p. 471 (1873) ("If we look at the reason of the law, we shall prefer" a rule that "discard[s] this doctrine of the necessity of a quickening"); I. Dana, Report of the Committee on the Production of Abortion, in 5 Transactions

a crime at all stages of pregnancy and authorized the imposition of severe punishment. See Lord Ellenborough's Act, 43 Geo. 3, c. 58 (1803). One scholar has suggested that Parliament's decision "may partly have been attributable to the medical man's concern that fetal life should be protected by the law at all stages of gestation." Keown 22.

In this country during the 19th century, the vast majority of the States enacted statutes criminalizing abortion at all stages of pregnancy. See Appendix A, *infra* (listing state statutory provisions in chronological order).³³ By 1868, the year when the Fourteenth Amendment was ratified, three-quarters of the States, 28 out of 37, had enacted statutes making abortion a crime even if it was performed before quickening.³⁴ See *ibid*. Of the nine States that had not yet

of the Maine Medical Association 37–39 (1866); Report on Criminal Abortion, in 12 Transactions of the American Medical Association 75–77 (1859); W. Guy, Principles of Medical Forensics 133–134 (1845); J. Chitty, Practical Treatise on Medical Jurisprudence 438 (2d Am. ed. 1836); 1 T. Beck & J. Beck, Elements of Medical Jurisprudence 293 (5th ed. 1823); 2 T. Percival, The Works, Literary, Moral and Medical 430 (1807); see also Keown 38–39 (collecting English authorities).

³³See generally Dellapenna 315–319 (cataloging the development of the law in the States); E. Quay, Justifiable Abortion—Medical and Legal Foundations, 49 Geo. L. J. 395, 435–437, 447–520 (1961) (Quay) (same); J. Witherspoon, Reexamining *Roe*: Nineteenth-Century Abortion Statutes and The Fourteenth Amendment, 17 St. Mary's L. J. 29, 34–36 (1985) (Witherspoon) (same).

 34 Some scholars assert that only 27 States prohibited abortion at all stages. See, e.g., Dellapenna 315; Witherspoon 34–35, and n. 15. Those scholars appear to have overlooked Rhode Island, which criminalized abortion at all stages in 1861. See Acts and Resolves R. I. 1861, ch. 371, $\S 1$, p. 133 (criminalizing the attempt to "procure the miscarriage" of "any pregnant woman" or "any woman supposed by such person to be pregnant," without mention of quickening). The amicus brief for the American Historical Association asserts that only 26 States prohibited abortion at all stages, but that brief incorrectly excludes West Virginia and Nebraska from its count. Compare Brief for American Historical Association 27–28 (citing Quay), with Appendix A, infra.

criminalized abortion at all stages, all but one did so by 1910. See *ibid*.

The trend in the Territories that would become the last 13 States was similar: All of them criminalized abortion at all stages of pregnancy between 1850 (the Kingdom of Hawaii) and 1919 (New Mexico). See Appendix B, *infra*; see also *Casey*, 505 U. S., at 952 (Rehnquist, C. J., concurring in judgment in part and dissenting in part); Dellapenna 317–319. By the end of the 1950s, according to the *Roe* Court's own count, statutes in all but four States and the District of Columbia prohibited abortion "however and whenever performed, unless done to save or preserve the life of the mother." 410 U. S., at 139.³⁵

This overwhelming consensus endured until the day *Roe* was decided. At that time, also by the *Roe* Court's own count, a substantial majority—30 States—still prohibited abortion at all stages except to save the life of the mother. See *id.*, at 118, and n. 2 (listing States). And though *Roe* discerned a "trend toward liberalization" in about "one-third of the States," those States still criminalized some abortions and regulated them more stringently than *Roe* would allow. *Id.*, at 140, and n. 37; Tribe 2. In short, the

³⁵The statutes of three States (Massachusetts, New Jersey, and Pennsylvania) prohibited abortions performed "unlawfully" or "without lawful justification." *Roe*, 410 U. S., at 139 (internal quotation marks omitted). In Massachusetts, case law held that abortion was allowed when, according to the judgment of physicians in the relevant community, the procedure was necessary to preserve the woman's life or her physical or emotional health. *Commonwealth* v. *Wheeler*, 315 Mass. 394, 395, 53 N. E. 2d 4, 5 (1944). In the other two States, however, there is no clear support in case law for the proposition that abortion was lawful where the mother's life was not at risk. See *State* v. *Brandenberg*, 137 N. J. L. 124, 58 A. 2d 709 (1948); *Commonwealth* v. *Trombetta*, 131 Pa. Super. 487, 200 A. 107 (1938).

Statutes in the two remaining jurisdictions (the District of Columbia and Alabama) permitted "abortion to preserve the mother's health." *Roe*, 410 U. S., at 139. Case law in those jurisdictions does not clarify the breadth of these exceptions.

"Court's opinion in *Roe* itself convincingly refutes the notion that the abortion liberty is deeply rooted in the history or tradition of our people." *Thornburgh* v. *American College of Obstetricians and Gynecologists*, 476 U. S. 747, 793 (1986) (White, J., dissenting).

d

The inescapable conclusion is that a right to abortion is not deeply rooted in the Nation's history and traditions. On the contrary, an unbroken tradition of prohibiting abortion on pain of criminal punishment persisted from the earliest days of the common law until 1973. The Court in *Roe* could have said of abortion exactly what *Glucksberg* said of assisted suicide: "Attitudes toward [abortion] have changed since Bracton, but our laws have consistently condemned, and continue to prohibit, [that practice]." 521 U. S., at 719.

3

Respondents and their *amici* have no persuasive answer to this historical evidence.

Neither respondents nor the Solicitor General disputes the fact that by 1868 the vast majority of States criminalized abortion at all stages of pregnancy. See Brief for Petitioners 12–13; see also Brief for American Historical Association et al. as *Amici Curiae* 27–28, and nn. 14–15 (conceding that 26 out of 37 States prohibited abortion before quickening); Tr. of Oral Arg. 74–75 (respondents' counsel conceding the same). Instead, respondents are forced to argue that it "does [not] matter that some States prohibited abortion at the time *Roe* was decided or when the Fourteenth Amendment was adopted." Brief for Respondents 21. But that argument flies in the face of the standard we have applied in determining whether an asserted right that is nowhere mentioned in the Constitution is nevertheless protected by the Fourteenth Amendment.

Not only are respondents and their *amici* unable to show

that a constitutional right to abortion was established when the Fourteenth Amendment was adopted, but they have found no support for the existence of an abortion right that predates the latter part of the 20th century—no state constitutional provision, no statute, no judicial decision, no learned treatise. The earliest sources called to our attention are a few district court and state court decisions decided shortly before *Roe* and a small number of law review articles from the same time period.³⁶

A few of respondents' *amici* muster historical arguments, but they are very weak. The Solicitor General repeats *Roe*'s claim that it is "'doubtful' . . . 'abortion was ever firmly established as a common-law crime even with respect to the destruction of a quick fetus." Brief for United States 26 (quoting *Roe*, 410 U. S., at 136). But as we have seen, great common-law authorities like Bracton, Coke, Hale, and Blackstone all wrote that a post-quickening abortion was a crime—and a serious one at that. Moreover, Hale and Blackstone (and many other authorities following them) asserted that even a pre-quickening abortion was "unlawful" and that, as a result, an abortionist was guilty of murder if the woman died from the attempt.

Instead of following these authorities, *Roe* relied largely on two articles by a pro-abortion advocate who claimed that Coke had intentionally misstated the common law because of his strong anti-abortion views.³⁷ These articles have

³⁶ See 410 U. S., at 154–155 (collecting cases decided between 1970 and 1973); C. Means, The Phoenix of Abortional Freedom: Is a Penumbral or Ninth-Amendment Right About To Arise From the Nineteenth-Century Legislative Ashes of a Fourteenth-Century Common-Law Liberty? 17 N. Y. L. Forum 335, 337–339 (1971) (Means II); C. Means, The Law of New York Concerning Abortion and the Status of the Foetus, 1664–1968: A Case of Cessation of Constitutionality, 14 N. Y. L. Forum 411 (1968) (Means I); Lucas 730.

³⁷See 410 U. S., at 136, n. 26 (citing Means II); 410 U. S., at 132–133, n. 21 (citing Means I).

been discredited,³⁸ and it has come to light that even members of Jane Roe's legal team did not regard them as serious scholarship. An internal memorandum characterized this author's work as donning "the guise of impartial scholarship while advancing the proper ideological goals." Continued reliance on such scholarship is unsupportable.

The Solicitor General next suggests that history supports an abortion right because the common law's failure to criminalize abortion before quickening means that "at the Founding and for decades thereafter, women generally could terminate a pregnancy, at least in its early stages." Brief for United States 26–27; see also Brief for Respondents 21. But the insistence on quickening was not universal, see *Mills*, 13 Pa., at 633; *State* v. *Slagle*, 83 N. C. 630, 632 (1880), and regardless, the fact that many States in the

³⁸ For critiques of Means's work, see, *e.g.*, Dellapenna 143–152, 325–331; Keown 3–12; J. Finnis, "Shameless Acts" in Colorado: Abuse of Scholarship in Constitutional Cases, 7 Academic Questions 10, 11–12 (1994); R. Destro, Abortion and the Constitution: The Need for a Life-Protective Amendment, 63 Cal. L. Rev. 1250, 1267–1282 (1975); R. Byrn, An American Tragedy: The Supreme Court on Abortion, 41 Ford. L. Rev. 807, 814–829 (1973).

³⁹Garrow 500–501, and n. 41 (internal quotation marks omitted).

⁴⁰In any event, Roe, Casey, and other related abortion decisions imposed substantial restrictions on a State's capacity to regulate abortions performed after quickening. See, e.g., June Medical Services L. L. C. v. Russo, 591 U.S. (2020) (holding a law requiring doctors performing abortions to secure admitting privileges to be unconstitutional); Whole Woman's Health v. Hellerstedt, 579 U. S. 582 (2016) (similar); Casey, 505 U.S., at 846 (declaring that prohibitions on "abortion before viability" are unconstitutional); id., at 887–898 (holding that a spousal notification provision was unconstitutional). In addition, Doe v. Bolton, 410 U. S. 179 (1973), has been interpreted by some to protect a broad right to obtain an abortion at any stage of pregnancy provided that a physician is willing to certify that it is needed due to a woman's "emotional" needs or "familial" concerns. Id., at 192. See, e.g., Women's Medical Professional Corp. v. Voinovich, 130 F. 3d 187, 209 (CA6 1997), cert. denied, 523 U. S. 1036 (1998); but see id., at 1039 (THOMAS, J., dissenting from denial of certiorari).

late 18th and early 19th century did not criminalize prequickening abortions does not mean that anyone thought the States lacked the authority to do so. When legislatures began to exercise that authority as the century wore on, no one, as far as we are aware, argued that the laws they enacted violated a fundamental right. That is not surprising since common-law authorities had repeatedly condemned abortion and described it as an "unlawful" act without regard to whether it occurred before or after quickening. See *supra*, at 16–21.

Another *amicus* brief relied upon by respondents (see Brief for Respondents 21) tries to dismiss the significance of the state criminal statutes that were in effect when the Fourteenth Amendment was adopted by suggesting that they were enacted for illegitimate reasons. According to this account, which is based almost entirely on statements made by one prominent proponent of the statutes, important motives for the laws were the fear that Catholic immigrants were having more babies than Protestants and that the availability of abortion was leading White Protestant women to "shir[k their] maternal duties." Brief for American Historical Association et al. as *Amici Curiae* 20.

Resort to this argument is a testament to the lack of any real historical support for the right that *Roe* and *Casey* recognized. This Court has long disfavored arguments based on alleged legislative motives. See, e.g., Erie v. Pap's A. M., 529 U. S. 277, 292 (2000) (plurality opinion); Turner Broadcasting System, Inc. v. FCC, 512 U. S. 622, 652 (1994); United States v. O'Brien, 391 U. S. 367, 383 (1968); Arizona v. California, 283 U. S. 423, 455 (1931) (collecting cases). The Court has recognized that inquiries into legislative motives "are a hazardous matter." O'Brien, 391 U. S., at 383. Even when an argument about legislative motive is backed by statements made by legislators who voted for a law, we

have been reluctant to attribute those motives to the legislative body as a whole. "What motivates one legislator to make a speech about a statute is not necessarily what motivates scores of others to enact it." *Id.*, at 384.

Here, the argument about legislative motive is not even based on statements by legislators, but on statements made by a few supporters of the new 19th-century abortion laws, and it is quite a leap to attribute these motives to all the legislators whose votes were responsible for the enactment of those laws. Recall that at the time of the adoption of the Fourteenth Amendment, over three-quarters of the States had adopted statutes criminalizing abortion (usually at all stages of pregnancy), and that from the early 20th century until the day *Roe* was handed down, every single State had such a law on its books. Are we to believe that the hundreds of lawmakers whose votes were needed to enact these laws were motivated by hostility to Catholics and women?

There is ample evidence that the passage of these laws was instead spurred by a sincere belief that abortion kills a human being. Many judicial decisions from the late 19th and early 20th centuries made that point. See, e.g., Nash v. Meyer, 54 Idaho 283, 301, 31 P. 2d 273, 280 (1934); State v. Ausplund, 86 Ore. 121, 131–132, 167 P. 1019, 1022–1023 (1917); Trent v. State, 15 Ala. App. 485, 488, 73 S. 834, 836 (1916); State v. Miller, 90 Kan. 230, 233, 133 P. 878, 879 (1913); State v. Tippie, 89 Ohio St. 35, 39–40, 105 N. E. 75, 77 (1913); State v. Gedicke, 43 N. J. L. 86, 90 (1881); Dougherty v. People, 1 Colo. 514, 522–523 (1873); State v. Moore, 25 Iowa 128, 131–132 (1868); Smith, 33 Me., at 57; see also Memphis Center for Reproductive Health v. Slatery, 14 F. 4th 409, 446, and n. 11 (CA6 2021) (Thapar, J., concurring in judgment in part and dissenting in part) (citing cases).

One may disagree with this belief (and our decision is not based on any view about when a State should regard prenatal life as having rights or legally cognizable interests),

but even *Roe* and *Casey* did not question the good faith of abortion opponents. See, *e.g.*, *Casey*, 505 U. S., at 850 ("Men and women of good conscience can disagree . . . about the profound moral and spiritual implications of terminating a pregnancy even in its earliest stage"). And we see no reason to discount the significance of the state laws in question based on these *amici*'s suggestions about legislative motive.⁴¹

C 1

Instead of seriously pressing the argument that the abortion right itself has deep roots, supporters of *Roe* and *Casey* contend that the abortion right is an integral part of a broader entrenched right. *Roe* termed this a right to privacy, 410 U. S., at 154, and *Casey* described it as the freedom to make "intimate and personal choices" that are "central to personal dignity and autonomy," 505 U. S., at 851. *Casey* elaborated: "At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life." *Ibid*.

The Court did not claim that this broadly framed right is absolute, and no such claim would be plausible. While individuals are certainly free to think and to say what they

⁴¹Other *amicus* briefs present arguments about the motives of proponents of liberal access to abortion. They note that some such supporters have been motivated by a desire to suppress the size of the African-American population. See Brief for African-American Organization et al. as *Amici Curiae* 14–21; see also *Box* v. *Planned Parenthood of Ind. and Ky., Inc.*, 587 U. S. ___, _____ (2019) (Thomas, J., concurring) (slip op., at 1–4). And it is beyond dispute that *Roe* has had that demographic effect. A highly disproportionate percentage of aborted fetuses are Black. See, *e.g.*, Dept. of Health and Human Servs., Centers for Disease Control and Prevention (CDC), K. Kortsmit et al., Abortion Surveillance—United States, 2019, 70 Morbidity and Mortality Report, Surveillance Summaries, p. 20 (Nov. 26, 2021) (Table 6). For our part, we do not question the motives of either those who have supported or those who have opposed laws restricting abortions.

wish about "existence," "meaning," the "universe," and "the mystery of human life," they are not always free *to act* in accordance with those thoughts. License to act on the basis of such beliefs may correspond to one of the many understandings of "liberty," but it is certainly not "ordered liberty."

Ordered liberty sets limits and defines the boundary between competing interests. *Roe* and *Casey* each struck a particular balance between the interests of a woman who wants an abortion and the interests of what they termed "potential life." *Roe*, 410 U. S., at 150 (emphasis deleted); *Casey*, 505 U. S., at 852. But the people of the various States may evaluate those interests differently. In some States, voters may believe that the abortion right should be even more extensive than the right that *Roe* and *Casey* recognized. Voters in other States may wish to impose tight restrictions based on their belief that abortion destroys an "unborn human being." Miss. Code Ann. §41–41–191(4)(b). Our Nation's historical understanding of ordered liberty does not prevent the people's elected representatives from deciding how abortion should be regulated.

Nor does the right to obtain an abortion have a sound basis in precedent. Casey relied on cases involving the right to marry a person of a different race, Loving v. Virginia, 388 U. S. 1 (1967); the right to marry while in prison, Turner v. Safley, 482 U. S. 78 (1987); the right to obtain contraceptives, Griswold v. Connecticut, 381 U. S. 479 (1965), Eisenstadt v. Baird, 405 U. S. 438 (1972), Carey v. Population Services Int'l, 431 U. S. 678 (1977); the right to reside with relatives, Moore v. East Cleveland, 431 U. S. 494 (1977); the right to make decisions about the education of one's children, Pierce v. Society of Sisters, 268 U. S. 510 (1925), Meyer v. Nebraska, 262 U. S. 390 (1923); the right not to be sterilized without consent, Skinner v. Oklahoma ex rel. Williamson, 316 U. S. 535 (1942); and the right in certain circumstances not to undergo involuntary surgery, forced

administration of drugs, or other substantially similar procedures, Winston v. Lee, 470 U. S. 753 (1985), Washington v. Harper, 494 U. S. 210 (1990), Rochin v. California, 342 U. S. 165 (1952). Respondents and the Solicitor General also rely on post-Casey decisions like Lawrence v. Texas, 539 U. S. 558 (2003) (right to engage in private, consensual sexual acts), and Obergefell v. Hodges, 576 U. S. 644 (2015) (right to marry a person of the same sex). See Brief for Respondents 18; Brief for United States 23–24.

These attempts to justify abortion through appeals to a broader right to autonomy and to define one's "concept of existence" prove too much. *Casey*, 505 U. S., at 851. Those criteria, at a high level of generality, could license fundamental rights to illicit drug use, prostitution, and the like. See *Compassion in Dying* v. *Washington*, 85 F. 3d 1440, 1444 (CA9 1996) (O'Scannlain, J., dissenting from denial of rehearing en banc). None of these rights has any claim to being deeply rooted in history. *Id.*, at 1440, 1445.

What sharply distinguishes the abortion right from the rights recognized in the cases on which *Roe* and *Casey* rely is something that both those decisions acknowledged: Abortion destroys what those decisions call "potential life" and what the law at issue in this case regards as the life of an "unborn human being." See *Roe*, 410 U. S., at 159 (abortion is "inherently different"); *Casey*, 505 U. S., at 852 (abortion is "a unique act"). None of the other decisions cited by *Roe* and *Casey* involved the critical moral question posed by abortion. They are therefore inapposite. They do not support the right to obtain an abortion, and by the same token, our conclusion that the Constitution does not confer such a right does not undermine them in any way.

9

In drawing this critical distinction between the abortion right and other rights, it is not necessary to dispute *Casey*'s claim (which we accept for the sake of argument) that "the

specific practices of States at the time of the adoption of the Fourteenth Amendment" do not "mar[k] the outer limits of the substantive sphere of liberty which the Fourteenth Amendment protects." 505 U. S., at 848. Abortion is nothing new. It has been addressed by lawmakers for centuries, and the fundamental moral question that it poses is ageless.

Defenders of *Roe* and *Casey* do not claim that any new scientific learning calls for a different answer to the underlying moral question, but they do contend that changes in society require the recognition of a constitutional right to obtain an abortion. Without the availability of abortion, they maintain, people will be inhibited from exercising their freedom to choose the types of relationships they desire, and women will be unable to compete with men in the workplace and in other endeavors.

Americans who believe that abortion should be restricted press countervailing arguments about modern developments. They note that attitudes about the pregnancy of unmarried women have changed drastically; that federal and state laws ban discrimination on the basis of pregnancy;⁴² that leave for pregnancy and childbirth are now guaranteed by law in many cases;⁴³ that the costs of medical care asso-

⁴² See, e.g., Pregnancy Discrimination Act, 92 Stat. 2076, 42 U. S. C. §2000e(k) (federal law prohibiting pregnancy discrimination in employment); Dept. of Labor, Women's Bureau, Employment Protections for Workers Who Are Pregnant or Nursing, https://www.dol.gov/agencies/wb/pregnant-nursing-employment-protections (showing that 46 States and the District of Columbia have employment protections against pregnancy discrimination).

⁴³See, e.g., Family and Medical Leave Act of 1993, 107 Stat. 9, 29 U. S. C. §2612 (federal law guaranteeing employment leave for pregnancy and birth); Bureau of Labor Statistics, Access to Paid and Unpaid Family Leave in 2018, https://www.bls.gov/opub/ted/2019/access-to-paid-

ciated with pregnancy are covered by insurance or government assistance;⁴⁴ that States have increasingly adopted "safe haven" laws, which generally allow women to drop off babies anonymously;⁴⁵ and that a woman who puts her newborn up for adoption today has little reason to fear that the baby will not find a suitable home.⁴⁶ They also claim that many people now have a new appreciation of fetal life and that when prospective parents who want to have a child view a sonogram, they typically have no doubt that what they see is their daughter or son.

and-unpaid-family-leave-in-2018.htm (showing that 89 percent of civilian workers had access to unpaid family leave in 2018).

⁴⁴The Affordable Care Act (ACA) requires non-grandfathered health plans in the individual and small group markets to cover certain essential health benefits, which include maternity and newborn care. See 124 Stat. 163, 42 U. S. C. §18022(b)(1)(D). The ACA also prohibits annual limits, see §300gg–11, and limits annual cost-sharing obligations on such benefits, §18022(c). State Medicaid plans must provide coverage for pregnancy-related services—including, but not limited to, prenatal care, delivery, and postpartum care—as well as services for other conditions that might complicate the pregnancy. 42 CFR §\$440.210(a)(2)(i)–(ii) (2020). State Medicaid plans are also prohibited from imposing deductions, cost-sharing, or similar charges for pregnancy-related services for pregnant women. 42 U. S. C. §\$1396o(a)(2)(B), (b)(2)(B).

⁴⁵Since *Casey*, all 50 States and the District of Columbia have enacted such laws. Dept. of Health and Human Servs., Children's Bureau, Infant Safe Haven Laws 1–2 (2016), https://www.childwelfare.gov/pubPDFs/safehaven.pdf (noting that safe haven laws began in Texas in 1999).

⁴⁶See, e.g., CDC, Adoption Experiences of Women and Men and Demand for Children To Adopt by Women 18–44 Years of Age in the United States 16 (Aug. 2008) ("[N]early 1 million women were seeking to adopt children in 2002 (i.e., they were in demand for a child), whereas the domestic supply of infants relinquished at birth or within the first month of life and available to be adopted had become virtually nonexistent"); CDC, National Center for Health Statistics, Adoption and Nonbiological Parenting, https://www.cdc.gov/nchs/nsfg/key_statistics/a-keystat.htm# adoption (showing that approximately 3.1 million women between the ages of 18–49 had ever "[t]aken steps to adopt a child" based on data collected from 2015–2019).

Both sides make important policy arguments, but supporters of *Roe* and *Casey* must show that this Court has the authority to weigh those arguments and decide how abortion may be regulated in the States. They have failed to make that showing, and we thus return the power to weigh those arguments to the people and their elected representatives.

D 1

The dissent is very candid that it cannot show that a constitutional right to abortion has any foundation, let alone a "'deeply rooted" one, "in this Nation's history and tradition." Glucksberg, 521 U.S., at 721; see post, at 12-14 (joint opinion of BREYER, SOTOMAYOR, and KAGAN, JJ.). The dissent does not identify any pre-Roe authority that supports such a right—no state constitutional provision or statute, no federal or state judicial precedent, not even a scholarly treatise. Compare post, at 12–14, n. 2, with supra, at 15–16, and n. 23. Nor does the dissent dispute the fact that abortion was illegal at common law at least after quickening; that the 19th century saw a trend toward criminalization of pre-quickening abortions; that by 1868, a supermajority of States (at least 26 of 37) had enacted statutes criminalizing abortion at all stages of pregnancy; that by the late 1950s at least 46 States prohibited abortion "however and whenever performed" except if necessary to save "the life of the mother," Roe, 410 U.S., at 139; and that when Roe was decided in 1973 similar statutes were still in effect in 30 States. Compare post, at 12–14, nn. 2–3, with *supra*, at 23–25, and nn. 33–34.47

The dissent's failure to engage with this long tradition is

⁴⁷By way of contrast, at the time *Griswold* v. *Connecticut*, 381 U. S. 479 (1965), was decided, the Connecticut statute at issue was an extreme outlier. See Brief for Planned Parenthood Federation of America, Inc. as *Amicus Curiae* in *Griswold* v. *Connecticut*, O. T. 1964, No. 496, p. 27.

devastating to its position. We have held that the "established method of substantive-due-process analysis" requires that an unenumerated right be "'deeply rooted in this Nation's history and tradition'" before it can be recognized as a component of the "liberty" protected in the Due Process Clause. *Glucksberg*, 521 U. S., at 721; cf. *Timbs*, 586 U. S., at ___ (slip op., at 7). But despite the dissent's professed fidelity to *stare decisis*, it fails to seriously engage with that important precedent—which it cannot possibly satisfy.

The dissent attempts to obscure this failure by misrepresenting our application of *Glucksberg*. The dissent suggests that we have focused only on "the legal status of abortion in the 19th century," *post*, at 26, but our review of this Nation's tradition extends well past that period. As explained, for more than a century after 1868—including "another half-century" after women gained the constitutional right to vote in 1920, see *post*, at 15; Amdt. 19—it was firmly established that laws prohibiting abortion like the Texas law at issue in *Roe* were permissible exercises of state regulatory authority. And today, another half century later, more than half of the States have asked us to overrule *Roe* and *Casey*. The dissent cannot establish that a right to abortion has *ever* been part of this Nation's tradition.

2

Because the dissent cannot argue that the abortion right is rooted in this Nation's history and tradition, it contends that the "constitutional tradition" is "not captured whole at a single moment," and that its "meaning gains content from the long sweep of our history and from successive judicial precedents." *Post*, at 18 (internal quotation marks omitted). This vague formulation imposes no clear restraints on what Justice White called the "exercise of raw judicial power," *Roe*, 410 U. S., at 222 (dissenting opinion), and while the dissent claims that its standard "does not mean

anything goes," *post*, at 17, any real restraints are hard to discern.

The largely limitless reach of the dissenters' standard is illustrated by the way they apply it here. First, if the "long sweep of history" imposes any restraint on the recognition of unenumerated rights, then *Roe* was surely wrong, since abortion was never allowed (except to save the life of the mother) in a majority of States for over 100 years before that decision was handed down. Second, it is impossible to defend *Roe* based on prior precedent because all of the precedents *Roe* cited, including *Griswold* and *Eisenstadt*, were critically different for a reason that we have explained: None of those cases involved the destruction of what *Roe* called "potential life." See *supra*, at 32.

So without support in history or relevant precedent, *Roe*'s reasoning cannot be defended even under the dissent's proposed test, and the dissent is forced to rely solely on the fact that a constitutional right to abortion was recognized in *Roe* and later decisions that accepted *Roe*'s interpretation. Under the doctrine of *stare decisis*, those precedents are entitled to careful and respectful consideration, and we engage in that analysis below. But as the Court has reiterated time and time again, adherence to precedent is not "an inexorable command." *Kimble* v. *Marvel Entertainment*, *LLC*, 576 U. S. 446, 455 (2015). There are occasions when past decisions should be overruled, and as we will explain, this is one of them.

3

The most striking feature of the dissent is the absence of any serious discussion of the legitimacy of the States' interest in protecting fetal life. This is evident in the analogy that the dissent draws between the abortion right and the rights recognized in *Griswold* (contraception), *Eisenstadt* (same), *Lawrence* (sexual conduct with member of the same sex), and *Obergefell* (same-sex marriage). Perhaps this is

designed to stoke unfounded fear that our decision will imperil those other rights, but the dissent's analogy is objectionable for a more important reason: what it reveals about the dissent's views on the protection of what *Roe* called "potential life." The exercise of the rights at issue in *Griswold*, *Eisenstadt*, *Lawrence*, and *Obergefell* does not destroy a "potential life," but an abortion has that effect. So if the rights at issue in those cases are fundamentally the same as the right recognized in *Roe* and *Casey*, the implication is clear: The Constitution does not permit the States to regard the destruction of a "potential life" as a matter of any significance.

That view is evident throughout the dissent. The dissent has much to say about the effects of pregnancy on women, the burdens of motherhood, and the difficulties faced by poor women. These are important concerns. However, the dissent evinces no similar regard for a State's interest in protecting prenatal life. The dissent repeatedly praises the "balance," post, at 2, 6, 8, 10, 12, that the viability line strikes between a woman's liberty interest and the State's interest in prenatal life. But for reasons we discuss later, see infra, at 50–54, 55–56, and given in the opinion of THE CHIEF JUSTICE, post, at 2–5 (opinion concurring in judgment), the viability line makes no sense. It was not adequately justified in *Roe*, and the dissent does not even try to defend it today. Nor does it identify any other point in a pregnancy after which a State is permitted to prohibit the destruction of a fetus.

Our opinion is not based on any view about if and when prenatal life is entitled to any of the rights enjoyed after birth. The dissent, by contrast, would impose on the people a particular theory about when the rights of personhood begin. According to the dissent, the Constitution requires the States to regard a fetus as lacking even the most basic human right—to live—at least until an arbitrary point in a pregnancy has passed. Nothing in the Constitution or in

our Nation's legal traditions authorizes the Court to adopt that "'theory of life.'" *Post*, at 8.

Ш

We next consider whether the doctrine of stare decisis counsels continued acceptance of Roe and Casev. Stare decisis plays an important role in our case law, and we have explained that it serves many valuable ends. It protects the interests of those who have taken action in reliance on a past decision. See Casey, 505 U.S., at 856 (joint opinion); see also Payne v. Tennessee, 501 U.S. 808, 828 (1991). It "reduces incentives for challenging settled precedents, saving parties and courts the expense of endless relitigation." Kimble, 576 U.S., at 455. It fosters "evenhanded" decisionmaking by requiring that like cases be decided in a like manner. Payne, 501 U.S., at 827. It "contributes to the actual and perceived integrity of the judicial process." *Ibid*. And it restrains judicial hubris and reminds us to respect the judgment of those who have grappled with important questions in the past. "Precedent is a way of accumulating and passing down the learning of past generations, a font of established wisdom richer than what can be found in any single judge or panel of judges." N. Gorsuch, A Republic, If You Can Keep It 217 (2019).

We have long recognized, however, that stare decisis is "not an inexorable command," Pearson v. Callahan, 555 U. S. 223, 233 (2009) (internal quotation marks omitted), and it "is at its weakest when we interpret the Constitution," Agostini v. Felton, 521 U. S. 203, 235 (1997). It has been said that it is sometimes more important that an issue "be settled than that it be settled right." Kimble, 576 U. S., at 455 (quoting Burnet v. Coronado Oil & Gas Co., 285 U. S. 393, 406 (1932) (Brandeis, J., dissenting)). But when it comes to the interpretation of the Constitution—the "great charter of our liberties," which was meant "to en-

dure through a long lapse of ages," *Martin* v. *Hunter's Lessee*, 1 Wheat. 304, 326 (1816) (opinion for the Court by Story, J.)—we place a high value on having the matter "settled right." In addition, when one of our constitutional decisions goes astray, the country is usually stuck with the bad decision unless we correct our own mistake. An erroneous constitutional decision can be fixed by amending the Constitution, but our Constitution is notoriously hard to amend. See Art. V; *Kimble*, 576 U. S., at 456. Therefore, in appropriate circumstances we must be willing to reconsider and, if necessary, overrule constitutional decisions.

Some of our most important constitutional decisions have overruled prior precedents. We mention three. In *Brown* v. *Board of Education*, 347 U. S. 483 (1954), the Court repudiated the "separate but equal" doctrine, which had allowed States to maintain racially segregated schools and other facilities. *Id.*, at 488 (internal quotation marks omitted). In so doing, the Court overruled the infamous decision in *Plessy* v. *Ferguson*, 163 U. S. 537 (1896), along with six other Supreme Court precedents that had applied the separate-but-equal rule. See *Brown*, 347 U. S., at 491.

In West Coast Hotel Co. v. Parrish, 300 U. S. 379 (1937), the Court overruled Adkins v. Children's Hospital of D. C., 261 U. S. 525 (1923), which had held that a law setting minimum wages for women violated the "liberty" protected by the Fifth Amendment's Due Process Clause. Id., at 545. West Coast Hotel signaled the demise of an entire line of important precedents that had protected an individual liberty right against state and federal health and welfare legislation. See Lochner v. New York, 198 U. S. 45 (1905) (holding invalid a law setting maximum working hours); Coppage v. Kansas, 236 U. S. 1 (1915) (holding invalid a law banning contracts forbidding employees to join a union); Jay Burns Baking Co. v. Bryan, 264 U. S. 504 (1924) (holding invalid laws fixing the weight of loaves of bread).

Finally, in West Virginia Bd. of Ed. v. Barnette, 319 U. S.

624 (1943), after the lapse of only three years, the Court overruled *Minersville School Dist.* v. *Gobitis*, 310 U. S. 586 (1940), and held that public school students could not be compelled to salute the flag in violation of their sincere beliefs. *Barnette* stands out because nothing had changed during the intervening period other than the Court's belated recognition that its earlier decision had been seriously wrong.

On many other occasions, this Court has overruled important constitutional decisions. (We include a partial list in the footnote that follows.⁴⁸) Without these decisions,

⁴⁸See, e.g., Obergefell v. Hodges, 576 U. S. 644 (2015) (right to samesex marriage), overruling Baker v. Nelson, 409 U. S. 810 (1972); Citizens United v. Federal Election Comm'n, 558 U.S. 310 (2010) (right to engage in campaign-related speech), overruling Austin v. Michigan Chamber of Commerce, 494 U. S. 652 (1990), and partially overruling McConnell v. Federal Election Comm'n, 540 U. S. 93 (2003); Montejo v. Louisiana, 556 U. S. 778 (2009) (Sixth Amendment right to counsel), overruling Michigan v. Jackson, 475 U. S. 625 (1986); Crawford v. Washington, 541 U. S. 36 (2004) (Sixth Amendment right to confront witnesses), overruling Ohio v. Roberts, 448 U. S. 56 (1980); Lawrence v. Texas, 539 U. S. 558 (2003) (right to engage in consensual, same-sex intimacy in one's home), overruling Bowers v. Hardwick, 478 U.S. 186 (1986); Ring v. Arizona, 536 U.S. 584 (2002) (Sixth Amendment right to a jury trial in capital prosecutions), overruling Walton v. Arizona, 497 U. S. 639 (1990); Agostini v. Felton, 521 U. S. 203 (1997) (evaluating whether government aid violates the Establishment Clause), overruling Aguilar v. Felton, 473 U. S. 402 (1985), and School Dist. of Grand Rapids v. Ball, 473 U. S. 373 (1985); Seminole Tribe of Fla. v. Florida, 517 U. S. 44 (1996) (lack of congressional power under the Indian Commerce Clause to abrogate States' Eleventh Amendment immunity), overruling Pennsylvania v. Union Gas Co., 491 U.S. 1 (1989); Payne v. Tennessee, 501 U.S. 808 (1991) (the Eighth Amendment does not erect a per se bar to the admission of victim impact evidence during the penalty phase of a capital trial), overruling Booth v. Maryland, 482 U. S. 496 (1987), and South Carolina v. Gathers, 490 U. S. 805 (1989); Batson v. Kentucky, 476 U. S. 79 (1986) (the Equal Protection Clause guarantees the defendant that the State will not exclude members of his race from the jury venire on account of race), overruling Swain v. Alabama, 380 U.S. 202 (1965); Garcia v. San Antonio

Metropolitan Transit Authority, 469 U.S. 528, 530 (1985) (rejecting the principle that the Commerce Clause does not empower Congress to enforce requirements, such as minimum wage laws, against the States "in areas of traditional governmental functions'"), overruling National League of Cities v. Usery, 426 U. S. 833 (1976); Illinois v. Gates, 462 U. S. 213 (1983) (the Fourth Amendment requires a totality of the circumstances approach for determining whether an informant's tip establishes probable cause), overruling Aguilar v. Texas, 378 U.S. 108 (1964), and Spinelli v. United States, 393 U. S. 410 (1969); United States v. Scott, 437 U. S. 82 (1978) (the Double Jeopardy Clause does not apply to Government appeals from orders granting defense motions to terminate a trial before verdict), overruling *United States* v. *Jenkins*, 420 U. S. 358 (1975); Craig v. Boren, 429 U.S. 190 (1976) (gender-based classifications are subject to intermediate scrutiny under the Equal Protection Clause), overruling Goesaert v. Cleary, 335 U. S. 464 (1948); Taylor v. Louisiana, 419 U.S. 522 (1975) (jury system which operates to exclude women from jury service violates the defendant's Sixth and Fourteenth Amendment right to an impartial jury), overruling Hoyt v. Florida, 368 U.S. 57 (1961); Brandenburg v. Ohio, 395 U. S. 444 (1969) (per curiam) (the mere advocacy of violence is protected under the First Amendment unless it is directed to incite or produce imminent lawless action), overruling Whitney v. California, 274 U. S. 357 (1927); Katz v. United States, 389 U. S. 347, 351 (1967) (Fourth Amendment "protects people, not places," and extends to what a person "seeks to preserve as private"), overruling Olmstead v. United States, 277 U.S. 438 (1928), and Goldman v. United States, 316 U. S. 129 (1942); Miranda v. Arizona, 384 U. S. 436 (1966) (procedural safeguards to protect the Fifth Amendment privilege against self-incrimination), overruling Crooker v. California, 357 U.S. 433 (1958), and Cicenia v. Lagay, 357 U. S. 504 (1958); Malloy v. Hogan, 378 U. S. 1 (1964) (the Fifth Amendment privilege against self-incrimination is also protected by the Fourteenth Amendment against abridgment by the States), overruling Twining v. New Jersey, 211 U. S. 78 (1908), and Adamson v. California, 332 U.S. 46 (1947); Wesberry v. Sanders, 376 U. S. 1, 7–8 (1964) (congressional districts should be apportioned so that "as nearly as is practicable one man's vote in a congressional election is to be worth as much as another's"), overruling in effect Colegrove v. Green, 328 U. S. 549 (1946); Gideon v. Wainwright, 372 U. S. 335 (1963) (right to counsel for indigent defendant in a criminal prosecution in state court under the Sixth and Fourteenth Amendments), overruling Betts v. Brady, 316 U. S. 455 (1942); Baker v. Carr, 369 U. S. 186 (1962) (federal courts have jurisdiction to consider constitutional challenges to state redistricting plans), effectively overruling in part Colegrove, 328 U.S. 549;

American constitutional law as we know it would be unrecognizable, and this would be a different country.

No Justice of this Court has ever argued that the Court should *never* overrule a constitutional decision, but overruling a precedent is a serious matter. It is not a step that should be taken lightly. Our cases have attempted to provide a framework for deciding when a precedent should be overruled, and they have identified factors that should be considered in making such a decision. *Janus* v. *State, County, and Municipal Employees*, 585 U. S. ___, ____ (2018) (slip op., at 34–35); *Ramos* v. *Louisiana*, 590 U. S. ___, ____ (2020) (KAVANAUGH, J., concurring in part) (slip op., at 7–9).

In this case, five factors weigh strongly in favor of overruling *Roe* and *Casey*: the nature of their error, the quality of their reasoning, the "workability" of the rules they imposed on the country, their disruptive effect on other areas of the law, and the absence of concrete reliance.

A

The nature of the Court's error. An erroneous interpretation of the Constitution is always important, but some are more damaging than others.

The infamous decision in *Plessy* v. *Ferguson*, was one

Mapp v. Ohio, 367 U. S. 643 (1961) (the exclusionary rule regarding the inadmissibility of evidence obtained in violation of the Fourth Amendment applies to the States), overruling Wolf v. Colorado, 338 U. S. 25 (1949); Smith v. Allwright, 321 U. S. 649 (1944) (racial restrictions on the right to vote in primary elections violates the Equal Protection Clause of the Fourteenth Amendment), overruling Grovey v. Townsend, 295 U. S. 45 (1935); United States v. Darby, 312 U. S. 100 (1941) (congressional power to regulate employment conditions under the Commerce Clause), overruling Hammer v. Dagenhart, 247 U. S. 251 (1918); Erie R. Co. v. Tompkins, 304 U. S. 64 (1938) (Congress does not have the power to declare substantive rules of common law; a federal court sitting in diversity jurisdiction must apply the substantive state law), overruling Swift v. Tyson, 16 Pet. 1 (1842).

such decision. It betrayed our commitment to "equality before the law." 163 U. S., at 562 (Harlan, J., dissenting). It was "egregiously wrong" on the day it was decided, see *Ramos*, 590 U. S., at ____ (opinion of KAVANAUGH, J.) (slip op., at 7), and as the Solicitor General agreed at oral argument, it should have been overruled at the earliest opportunity, see Tr. of Oral Arg. 92–93.

Roe was also egregiously wrong and deeply damaging. For reasons already explained, *Roe*'s constitutional analysis was far outside the bounds of any reasonable interpretation of the various constitutional provisions to which it vaguely pointed.

Roe was on a collision course with the Constitution from the day it was decided, Casey perpetuated its errors, and those errors do not concern some arcane corner of the law of little importance to the American people. Rather, wielding nothing but "raw judicial power," Roe, 410 U.S., at 222 (White, J., dissenting), the Court usurped the power to address a question of profound moral and social importance that the Constitution unequivocally leaves for the people. Casey described itself as calling both sides of the national controversy to resolve their debate, but in doing so, Casey necessarily declared a winning side. Those on the losing side—those who sought to advance the State's interest in fetal life—could no longer seek to persuade their elected representatives to adopt policies consistent with their views. The Court short-circuited the democratic process by closing it to the large number of Americans who dissented in any respect from Roe. "Roe fanned into life an issue that has inflamed our national politics in general, and has obscured with its smoke the selection of Justices to this Court in particular, ever since." Casey, 505 U.S., at 995-996 (opinion of Scalia, J.). Together, Roe and Casey represent an error that cannot be allowed to stand.

As the Court's landmark decision in *West Coast Hotel* illustrates, the Court has previously overruled decisions that

wrongly removed an issue from the people and the democratic process. As Justice White later explained, "decisions that find in the Constitution principles or values that cannot fairly be read into that document usurp the people's authority, for such decisions represent choices that the people have never made and that they cannot disavow through corrective legislation. For this reason, it is essential that this Court maintain the power to restore authority to its proper possessors by correcting constitutional decisions that, on reconsideration, are found to be mistaken." *Thornburgh*, 476 U. S., at 787 (dissenting opinion).

E

The quality of the reasoning. Under our precedents, the quality of the reasoning in a prior case has an important bearing on whether it should be reconsidered. See Janus, 585 U. S., at ____ (slip op., at 38); Ramos, 590 U. S., at ____ (opinion of KAVANAUGH, J.) (slip op., at 7–8). In Part II, supra, we explained why Roe was incorrectly decided, but that decision was more than just wrong. It stood on exceptionally weak grounds.

Roe found that the Constitution implicitly conferred a right to obtain an abortion, but it failed to ground its decision in text, history, or precedent. It relied on an erroneous historical narrative; it devoted great attention to and presumably relied on matters that have no bearing on the meaning of the Constitution; it disregarded the fundamental difference between the precedents on which it relied and the question before the Court; it concocted an elaborate set of rules, with different restrictions for each trimester of pregnancy, but it did not explain how this veritable code could be teased out of anything in the Constitution, the history of abortion laws, prior precedent, or any other cited source; and its most important rule (that States cannot protect fetal life prior to "viability") was never raised by any

party and has never been plausibly explained. *Roe*'s reasoning quickly drew scathing scholarly criticism, even from supporters of broad access to abortion.

The *Casey* plurality, while reaffirming *Roe*'s central holding, pointedly refrained from endorsing most of its reasoning. It revised the textual basis for the abortion right, silently abandoned *Roe*'s erroneous historical narrative, and jettisoned the trimester framework. But it replaced that scheme with an arbitrary "undue burden" test and relied on an exceptional version of *stare decisis* that, as explained below, this Court had never before applied and has never invoked since.

1 a

The weaknesses in *Roe's* reasoning are well-known. Without any grounding in the constitutional text, history, or precedent, it imposed on the entire country a detailed set of rules much like those that one might expect to find in a statute or regulation. See 410 U.S., at 163-164. Dividing pregnancy into three trimesters, the Court imposed special rules for each. During the first trimester, the Court announced, "the abortion decision and its effectuation must be left to the medical judgment of the pregnant woman's attending physician." Id., at 164. After that point, a State's interest in regulating abortion for the sake of a woman's health became compelling, and accordingly, a State could "regulate the abortion procedure in ways that are reasonably related to maternal health." *Ibid*. Finally, in "the stage subsequent to viability," which in 1973 roughly coincided with the beginning of the third trimester, the State's interest in "the potentiality of human life" became compelling, and therefore a State could "regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." Id., at 164–165.

This elaborate scheme was the Court's own brainchild. Neither party advocated the trimester framework; nor did either party or any *amicus* argue that "viability" should mark the point at which the scope of the abortion right and a State's regulatory authority should be substantially transformed. See Brief for Appellant and Brief for Appellee in *Roe* v. *Wade*, O. T. 1972, No. 70–18; see also C. Forsythe, Abuse of Discretion: The Inside Story of *Roe* v. *Wade* 127, 141 (2012).

b

Not only did this scheme resemble the work of a legislature, but the Court made little effort to explain how these rules could be deduced from any of the sources on which constitutional decisions are usually based. We have already discussed *Roe*'s treatment of constitutional text, and the opinion failed to show that history, precedent, or any other cited source supported its scheme.

Roe featured a lengthy survey of history, but much of its discussion was irrelevant, and the Court made no effort to explain why it was included. For example, multiple paragraphs were devoted to an account of the views and practices of ancient civilizations where infanticide was widely accepted. See 410 U.S., at 130–132 (discussing ancient Greek and Roman practices). When it came to the most important historical fact—how the States regulated abortion when the Fourteenth Amendment was adopted—the Court said almost nothing. It allowed that States had tightened their abortion laws "in the middle and late 19th century," *id.*, at 139, but it implied that these laws might have

⁴⁹ See, e.g., C. Patterson, "Not Worth the Rearing": The Causes of Infant Exposure in Ancient Greece, 115 Transactions Am. Philosophical Assn. 103, 111–123 (1985); A. Cameron, The Exposure of Children and Greek Ethics, 46 Classical Rev. 105–108 (1932); H. Bennett, The Exposure of Infants in Ancient Rome, 18 Classical J. 341–351 (1923); W. Harris, Child-Exposure in the Roman Empire, 84 J. Roman Studies 1 (1994).

been enacted not to protect fetal life but to further "a Victorian social concern" about "illicit sexual conduct," id., at 148.

Roe's failure even to note the overwhelming consensus of state laws in effect in 1868 is striking, and what it said about the common law was simply wrong. Relying on two discredited articles by an abortion advocate, the Court erroneously suggested—contrary to Bracton, Coke, Hale, Blackstone, and a wealth of other authority—that the common law had probably never really treated post-quickening abortion as a crime. See id., at 136 ("[I]t now appear[s] doubtful that abortion was ever firmly established as a common-law crime even with respect to the destruction of a quick fetus"). This erroneous understanding appears to have played an important part in the Court's thinking because the opinion cited "the lenity of the common law" as one of the four factors that informed its decision. Id., at 165.

After surveying history, the opinion spent many paragraphs conducting the sort of fact-finding that might be undertaken by a legislative committee. This included a lengthy account of the "position of the American Medical Association" and "[t]he position of the American Public Health Association," as well as the vote by the American Bar Association's House of Delegates in February 1972 on proposed abortion legislation. *Id.*, at 141, 144, 146 (emphasis deleted). Also noted were a British judicial decision handed down in 1939 and a new British abortion law enacted in 1967. *Id.*, at 137–138. The Court did not explain why these sources shed light on the meaning of the Constitution, and not one of them adopted or advocated anything like the scheme that *Roe* imposed on the country.

Finally, after all this, the Court turned to precedent. Citing a broad array of cases, the Court found support for a constitutional "right of personal privacy," *id.*, at 152, but it conflated two very different meanings of the term: the right

to shield information from disclosure and the right to make and implement important personal decisions without governmental interference. See *Whalen* v. *Roe*, 429 U. S. 589, 599–600 (1977). Only the cases involving this second sense of the term could have any possible relevance to the abortion issue, and some of the cases in that category involved personal decisions that were obviously very, very far afield. See *Pierce*, 268 U. S. 510 (right to send children to religious school); *Meyer*, 262 U. S. 390 (right to have children receive German language instruction).

What remained was a handful of cases having something to do with marriage, *Loving*, 388 U. S. 1 (right to marry a person of a different race), or procreation, *Skinner*, 316 U. S. 535 (right not to be sterilized); *Griswold*, 381 U. S. 479 (right of married persons to obtain contraceptives); *Eisenstadt*, 405 U. S. 438 (same, for unmarried persons). But none of these decisions involved what is distinctive about abortion: its effect on what *Roe* termed "potential life."

When the Court summarized the basis for the scheme it imposed on the country, it asserted that its rules were "consistent with" the following: (1) "the relative weights of the respective interests involved," (2) "the lessons and examples of medical and legal history," (3) "the lenity of the common law," and (4) "the demands of the profound problems of the present day." *Roe*, 410 U. S., at 165. Put aside the second and third factors, which were based on the Court's flawed account of history, and what remains are precisely the sort of considerations that legislative bodies often take into account when they draw lines that accommodate competing interests. The scheme *Roe* produced *looked* like legislation, and the Court provided the sort of explanation that might be expected from a legislative body.

c

What *Roe* did not provide was any cogent justification for the lines it drew. Why, for example, does a State have no

authority to regulate first trimester abortions for the purpose of protecting a woman's health? The Court's only explanation was that mortality rates for abortion at that stage were lower than the mortality rates for childbirth. *Id.*, at 163. But the Court did not explain why mortality rates were the only factor that a State could legitimately consider. Many health and safety regulations aim to avoid adverse health consequences short of death. And the Court did not explain why it departed from the normal rule that courts defer to the judgments of legislatures "in areas fraught with medical and scientific uncertainties." *Marshall* v. *United States*, 414 U. S. 417, 427 (1974).

An even more glaring deficiency was *Roe*'s failure to justify the critical distinction it drew between pre- and post-viability abortions. Here is the Court's entire explanation:

"With respect to the State's important and legitimate interest in potential life, the 'compelling' point is at viability. This is so because the fetus then presumably has the capability of meaningful life outside the womb." 410 U. S., at 163.

As Professor Laurence Tribe has written, "[c]learly, this mistakes 'a definition for a syllogism." Tribe 4 (quoting Ely 924). The definition of a "viable" fetus is one that is capable of surviving outside the womb, but why is this the point at which the State's interest becomes compelling? If, as Roe held, a State's interest in protecting prenatal life is compelling "after viability," 410 U. S., at 163, why isn't that interest "equally compelling before viability"? Webster v. Reproductive Health Services, 492 U. S. 490, 519 (1989) (plurality opinion) (quoting Thornburgh, 476 U. S., at 795 (White, J., dissenting)). Roe did not say, and no explanation is apparent

This arbitrary line has not found much support among philosophers and ethicists who have attempted to justify a right to abortion. Some have argued that a fetus should not

be entitled to legal protection until it acquires the characteristics that they regard as defining what it means to be a "person." Among the characteristics that have been offered as essential attributes of "personhood" are sentience, self-awareness, the ability to reason, or some combination thereof. ⁵⁰ By this logic, it would be an open question whether even born individuals, including young children or those afflicted with certain developmental or medical conditions, merit protection as "persons." But even if one takes the view that "personhood" begins when a certain attribute or combination of attributes is acquired, it is very hard to see why viability should mark the point where "personhood" begins.

The most obvious problem with any such argument is that viability is heavily dependent on factors that have nothing to do with the characteristics of a fetus. One is the

⁵⁰ See, e.g., P. Singer, Rethinking Life & Death 218 (1994) (defining a person as "a being with awareness of her or his own existence over time. and the capacity to have wants and plans for the future"); B. Steinbock, Life Before Birth: The Moral and Legal Status of Embryos and Fetuses 9-13 (1992) (arguing that "the possession of interests is both necessary and sufficient for moral status" and that the "capacity for conscious awareness is a necessary condition for the possession of interests" (emphasis deleted)); M. Warren, On the Moral and Legal Status of Abortion, 57 The Monist 1, 5 (1973) (arguing that, to qualify as a person, a being must have at least one of five traits that are "central to the concept of personhood": (1) "consciousness (of objects and events external and/or internal to the being), and in particular the capacity to feel pain": (2) "reasoning (the developed capacity to solve new and relatively complex problems)"; (3) "self-motivated activity (activity which is relatively independent of either genetic or direct external control)"; (4) "the capacity to communicate, by whatever means, messages of an indefinite variety of types"; and (5) "the presence of self-concepts, and self-awareness, either individual or racial, or both" (emphasis deleted)); M. Tooley, Abortion & Infanticide, 2 Philosophy & Pub. Affairs 37, 49 (Autumn 1972) (arguing that "having a right to life presupposes that one is capable of desiring to continue existing as a subject of experiences and other mental states").

state of neonatal care at a particular point in time. Due to the development of new equipment and improved practices, the viability line has changed over the years. In the 19th century, a fetus may not have been viable until the 32d or 33d week of pregnancy or even later.⁵¹ When *Roe* was decided, viability was gauged at roughly 28 weeks. See 410 U. S., at 160. Today, respondents draw the line at 23 or 24 weeks. Brief for Respondents 8. So, according to *Roe*'s logic, States now have a compelling interest in protecting a fetus with a gestational age of, say, 26 weeks, but in 1973 States did not have an interest in protecting an identical fetus. How can that be?

Viability also depends on the "quality of the available medical facilities." *Colautti* v. *Franklin*, 439 U. S. 379, 396 (1979). Thus, a 24-week-old fetus may be viable if a woman gives birth in a city with hospitals that provide advanced care for very premature babies, but if the woman travels to a remote area far from any such hospital, the fetus may no longer be viable. On what ground could the constitutional status of a fetus depend on the pregnant woman's location? And if viability is meant to mark a line having universal moral significance, can it be that a fetus that is viable in a big city in the United States has a privileged moral status

⁵¹ See W. Lusk, Science and the Art of Midwifery 74–75 (1882) (explaining that "[w]ith care, the life of a child born within [the eighth month of pregnancy] may be preserved"); *id.*, at 326 ("Where the choice lies with the physician, the provocation of labor is usually deferred until the thirty-third or thirty-fourth week"); J. Beck, Researches in Medicine and Medical Jurisprudence 68 (2d ed. 1835) ("Although children born before the completion of the seventh month have occasionally survived, and been reared, yet in a medico-legal point of view, no child ought to be considered as capable of sustaining an independent existence until the seventh month has been fully completed"); see also J. Baker, The Incubator and the Medical Discovery of the Premature Infant, J. Perinatology 322 (2000) (explaining that, in the 19th century, infants born at seven to eight months' gestation were unlikely to survive beyond "the first days of life").

not enjoyed by an identical fetus in a remote area of a poor country?

In addition, as the Court once explained, viability is not really a hard-and-fast line. *Ibid*. A physician determining a particular fetus's odds of surviving outside the womb must consider "a number of variables," including "gestational age," "fetal weight," a woman's "general health and nutrition," the "quality of the available medical facilities," and other factors. Id., at 395–396. It is thus "only with difficulty" that a physician can estimate the "probability" of a particular fetus's survival. *Id.*, at 396. And even if each fetus's probability of survival could be ascertained with certainty, settling on a "probabilit[y] of survival" that should count as "viability" is another matter. *Ibid*. Is a fetus viable with a 10 percent chance of survival? 25 percent? 50 percent? Can such a judgment be made by a State? And can a State specify a gestational age limit that applies in all cases? Or must these difficult questions be left entirely to the individual "attending physician on the particular facts of the case before him"? *Id.*, at 388.

The viability line, which *Casey* termed *Roe*'s central rule, makes no sense, and it is telling that other countries almost uniformly eschew such a line.⁵² The Court thus asserted raw judicial power to impose, as a matter of constitutional law, a uniform viability rule that allowed the States less freedom to regulate abortion than the majority of western democracies enjoy.

d

All in all, *Roe*'s reasoning was exceedingly weak, and academic commentators, including those who agreed with the

⁵²According to the Center for Reproductive Rights, only the United States and the Netherlands use viability as a gestational limit on the availability of abortion on-request. See Center for Reproductive Rights, The World's Abortion Laws (Feb. 23, 2021), https://reproductiverights.org/maps/worlds-abortion-laws.

decision as a matter of policy, were unsparing in their criticism. John Hart Ely famously wrote that Roe was "not constitutional law and g[ave] almost no sense of an obligation to try to be." Ely 947 (emphasis deleted). Archibald Cox, who served as Solicitor General under President Kennedy, commented that *Roe* "read[s] like a set of hospital rules and regulations" that "[n]either historian, layman, nor lawyer will be persuaded . . . are part of . . . the Constitution." The Role of the Supreme Court in American Government 113– 114 (1976). Laurence Tribe wrote that "even if there is a need to divide pregnancy into several segments with lines that clearly identify the limits of governmental power, 'interest-balancing' of the form the Court pursues fails to justify any of the lines actually drawn." Tribe 4–5. Mark Tushnet termed *Roe* a "totally unreasoned judicial opinion." Red, White, and Blue: A Critical Analysis of Constitutional Law 54 (1988). See also P. Bobbitt, Constitutional Fate 157 (1982); A. Amar, Foreword: The Document and the Doctrine, 114 Harv. L. Rev. 26, 110 (2000).

Despite Roe's weaknesses, its reach was steadily extended in the years that followed. The Court struck down laws requiring that second-trimester abortions be performed only in hospitals, Akron v. Akron Center for Reproductive Health, Inc., 462 U.S. 416, 433-439 (1983); that minors obtain parental consent, Planned Parenthood of Central Mo. v. Danforth, 428 U.S. 52, 74 (1976); that women give written consent after being informed of the status of the developing prenatal life and the risks of abortion, Akron, 462 U. S., at 442–445; that women wait 24 hours for an abortion, id., at 449–451; that a physician determine viability in a particular manner, Colautti, 439 U.S., at 390-397; that a physician performing a post-viability abortion use the technique most likely to preserve the life of the fetus, id., at 397–401; and that fetal remains be treated in a humane and sanitary manner, Akron, 462 U.S., at 451-452.

Justice White complained that the Court was engaging in "unrestrained imposition of its own extraconstitutional value preferences." *Thornburgh*, 476 U. S., at 794 (dissenting opinion). And the United States as *amicus curiae* asked the Court to overrule *Roe* five times in the decade before *Casey*, see 505 U. S., at 844 (joint opinion), and then asked the Court to overrule it once more in *Casey* itself.

2

When Casey revisited Roe almost 20 years later, very little of Roe's reasoning was defended or preserved. The Court abandoned any reliance on a privacy right and instead grounded the abortion right entirely on the Fourteenth Amendment's Due Process Clause. 505 U. S., at 846. The Court did not reaffirm Roe's erroneous account of abortion history. In fact, none of the Justices in the majority said anything about the history of the abortion right. And as for precedent, the Court relied on essentially the same body of cases that Roe had cited. Thus, with respect to the standard grounds for constitutional decisionmaking—text, history, and precedent—Casey did not attempt to bolster Roe's reasoning.

The Court also made no real effort to remedy one of the greatest weaknesses in *Roe*'s analysis: its much-criticized discussion of viability. The Court retained what it called *Roe*'s "central holding"—that a State may not regulate previability abortions for the purpose of protecting fetal life—but it provided no principled defense of the viability line. 505 U. S., at 860, 870–871. Instead, it merely rephrased what *Roe* had said, stating that viability marked the point at which "the independent existence of a second life can in reason and fairness be the object of state protection that now overrides the rights of the woman." 505 U. S., at 870. Why "reason and fairness" demanded that the line be drawn at viability the Court did not explain. And the Justices who authored the controlling opinion conspicuously

failed to say that they agreed with the viability rule; instead, they candidly acknowledged "the reservations [some] of us may have in reaffirming [that] holding of *Roe*." *Id.*, at 853.

The controlling opinion criticized and rejected *Roe*'s trimester scheme, 505 U.S., at 872, and substituted a new "undue burden" test, but the basis for this test was obscure. And as we will explain, the test is full of ambiguities and is difficult to apply.

Casey, in short, either refused to reaffirm or rejected important aspects of *Roe*'s analysis, failed to remedy glaring deficiencies in *Roe*'s reasoning, endorsed what it termed *Roe*'s central holding while suggesting that a majority might not have thought it was correct, provided no new support for the abortion right other than *Roe*'s status as precedent, and imposed a new and problematic test with no firm grounding in constitutional text, history, or precedent.

As discussed below, *Casey* also deployed a novel version of the doctrine of *stare decisis*. See *infra*, at 64–69. This new doctrine did not account for the profound wrongness of the decision in *Roe*, and placed great weight on an intangible form of reliance with little if any basis in prior case law. *Stare decisis* does not command the preservation of such a decision.

C

Workability. Our precedents counsel that another important consideration in deciding whether a precedent should be overruled is whether the rule it imposes is workable—that is, whether it can be understood and applied in a consistent and predictable manner. Montejo v. Louisiana, 556 U. S. 778, 792 (2009); Patterson v. McLean Credit Union, 491 U. S. 164, 173 (1989); Gulfstream Aerospace Corp. v. Mayacamas Corp., 485 U. S. 271, 283–284 (1988). Casey's "undue burden" test has scored poorly on the workability scale.

1

Problems begin with the very concept of an "undue burden." As Justice Scalia noted in his *Casey* partial dissent, determining whether a burden is "due" or "undue" is "inherently standardless." 505 U. S., at 992; see also *June Medical Services L. L. C.* v. *Russo*, 591 U. S. ____, ___ (2020) (GORSUCH, J., dissenting) (slip op., at 17) ("[W]hether a burden is deemed undue depends heavily on which factors the judge considers and how much weight he accords each of them" (internal quotation marks and alterations omitted)).

The *Casey* plurality tried to put meaning into the "undue burden" test by setting out three subsidiary rules, but these rules created their own problems. The first rule is that "a provision of law is invalid, if its purpose or effect is to place a *substantial obstacle* in the path of a woman seeking an abortion before the fetus attains viability." 505 U. S., at 878 (emphasis added); see also *id.*, at 877. But whether a particular obstacle qualifies as "substantial" is often open to reasonable debate. In the sense relevant here, "substantial" means "of ample or considerable amount, quantity, or size." Random House Webster's Unabridged Dictionary 1897 (2d ed. 2001). Huge burdens are plainly "substantial," and trivial ones are not, but in between these extremes, there is a wide gray area.

This ambiguity is a problem, and the second rule, which applies at all stages of a pregnancy, muddies things further. It states that measures designed "to ensure that the woman's choice is informed" are constitutional so long as they do not impose "an undue burden on the right." *Casey*, 505 U. S., at 878. To the extent that this rule applies to previability abortions, it overlaps with the first rule and appears to impose a different standard. Consider a law that imposes an insubstantial obstacle but serves little purpose. As applied to a pre-viability abortion, would such a regulation be constitutional on the ground that it does not impose a "substantial obstacle"? Or would it be unconstitutional on

the ground that it creates an "undue burden" because the burden it imposes, though slight, outweighs its negligible benefits? Casey does not say, and this ambiguity would lead to confusion down the line. Compare June Medical, 591 U. S., at _____ (plurality opinion) (slip op., at 1–2), with id., at _____ (ROBERTS, C. J., concurring) (slip op., at 5–6).

The third rule complicates the picture even more. Under that rule, "[u]nnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right." Casey, 505 U. S., at 878 (emphasis added). This rule contains no fewer than three vague terms. It includes the two already discussed—"undue burden" and "substantial obstacle"—even though they are inconsistent. And it adds a third ambiguous term when it refers to "unnecessary health regulations." The term "necessary" has a range of meanings—from "essential" to merely "useful." See Black's Law Dictionary 928 (5th ed. 1979); American Heritage Dictionary of the English Language 877 (1971). Casey did not explain the sense in which the term is used in this rule.

In addition to these problems, one more applies to all three rules. They all call on courts to examine a law's effect on women, but a regulation may have a very different impact on different women for a variety of reasons, including their places of residence, financial resources, family situations, work and personal obligations, knowledge about fetal development and abortion, psychological and emotional disposition and condition, and the firmness of their desire to obtain abortions. In order to determine whether a regulation presents a substantial obstacle to women, a court needs to know which set of women it should have in mind and how many of the women in this set must find that an obstacle is "substantial."

Casey provided no clear answer to these questions. It said that a regulation is unconstitutional if it imposes a

substantial obstacle "in a large fraction of cases in which [it] is relevant," 505 U. S., at 895, but there is obviously no clear line between a fraction that is "large" and one that is not. Nor is it clear what the Court meant by "cases in which" a regulation is "relevant." These ambiguities have caused confusion and disagreement. Compare Whole Woman's Health v. Hellerstedt, 579 U. S. 582, 627–628 (2016), with id., at 666–667, and n. 11 (ALITO, J., dissenting).

2

The difficulty of applying *Casey*'s new rules surfaced in that very case. The controlling opinion found that Pennsylvania's 24-hour waiting period requirement and its informed-consent provision did not impose "undue burden[s]," *Casey*, 505 U. S., at 881–887, but Justice Stevens, applying the same test, reached the opposite result, *id.*, at 920–922 (opinion concurring in part and dissenting in part). That did not bode well, and then-Chief Justice Rehnquist aptly observed that "the undue burden standard presents nothing more workable than the trimester framework." *Id.*, at 964–966 (dissenting opinion).

The ambiguity of the "undue burden" test also produced disagreement in later cases. In Whole Woman's Health, the Court adopted the cost-benefit interpretation of the test, stating that "[t]he rule announced in Casey . . . requires that courts consider the burdens a law imposes on abortion access together with the benefits those laws confer." 579 U. S., at 607 (emphasis added). But five years later, a majority of the Justices rejected that interpretation. See June Medical, 591 U. S. ____. Four Justices reaffirmed Whole Woman's Health's instruction to "weigh" a law's "benefits" against "the burdens it imposes on abortion access." 591 U. S., at ____ (plurality opinion) (slip op., at 2) (internal quotation marks omitted). But THE CHIEF JUSTICE—who cast

the deciding vote—argued that "[n]othing about *Casey* suggested that a weighing of costs and benefits of an abortion regulation was a job for the courts." *Id.*, at ____ (opinion concurring in judgment) (slip op., at 6). And the four Justices in dissent rejected the plurality's interpretation of *Casey*. See 591 U. S., at ____ (opinion of ALITO, J., joined in relevant part by THOMAS, GORSUCH, and KAVANAUGH, JJ.) (slip op., at 4); *id.*, at ____ (opinion of GORSUCH, J.) (slip op., at 15–18); *id.*, at ____ (opinion of KAVANAUGH, J.) (slip op., at 1–2) ("[F]ive Members of the Court reject the *Whole Woman's Health* cost-benefit standard").

This Court's experience applying *Casey* has confirmed Chief Justice Rehnquist's prescient diagnosis that the undue-burden standard was "not built to last." *Casey*, 505 U. S., at 965 (opinion concurring in judgment in part and dissenting in part).

3

The experience of the Courts of Appeals provides further evidence that *Casey*'s "line between" permissible and unconstitutional restrictions "has proved to be impossible to draw with precision." *Janus*, 585 U. S., at ____ (slip op., at 38).

Casey has generated a long list of Circuit conflicts. Most recently, the Courts of Appeals have disagreed about whether the balancing test from Whole Woman's Health correctly states the undue-burden framework.⁵³ They have disagreed on the legality of parental notification rules.⁵⁴

⁵³ Compare Whole Woman's Health v. Paxton, 10 F. 4th 430, 440 (CA5 2021), EMW Women's Surgical Center, P.S.C. v. Friedlander, 978 F. 3d 418, 437 (CA6 2020), and Hopkins v. Jegley, 968 F. 3d 912, 915 (CA8 2020) (per curiam), with Planned Parenthood of Ind. & Ky., Inc. v. Box, 991 F. 3d 740, 751–752 (CA7 2021).

⁵⁴ Compare Planned Parenthood of Blue Ridge v. Camblos, 155 F. 3d 352, 367 (CA4 1998), with Planned Parenthood of Ind. & Ky., Inc. v. Ad-

They have disagreed about bans on certain dilation and evacuation procedures.⁵⁵ They have disagreed about when an increase in the time needed to reach a clinic constitutes an undue burden.⁵⁶ And they have disagreed on whether a State may regulate abortions performed because of the fetus's race, sex, or disability.⁵⁷

The Courts of Appeals have experienced particular difficulty in applying the large-fraction-of-relevant-cases test. They have criticized the assignment while reaching unpredictable results.⁵⁸ And they have candidly outlined *Casey*'s many other problems.⁵⁹

ams, 937 F. 3d 973, 985–990 (CA7 2019), cert. granted, judgment vacated, 591 U. S. ___ (2020), and *Planned Parenthood, Sioux Falls Clinic* v. *Miller*, 63 F. 3d 1452, 1460 (CA8 1995).

⁵⁵Compare Whole Woman's Health v. Paxton, 10 F. 4th, at 435–436, with West Ala. Women's Center v. Williamson, 900 F. 3d 1310, 1319, 1327 (CA11 2018), and EMW Women's Surgical Center, P.S.C. v. Friedlander, 960 F. 3d 785, 806–808 (CA6 2020).

⁵⁶ Compare Tucson Woman's Clinic v. Eden, 379 F. 3d 531, 541 (CA9 2004), with Women's Medical Professional Corp. v. Baird, 438 F. 3d 595, 605 (CA6 2006), and Greenville Women's Clinic v. Bryant, 222 F. 3d 157, 171–172 (CA4 2000).

⁵⁷Compare Preterm-Cleveland v. McCloud, 994 F. 3d 512, 520–535 (CA6 2021), with Little Rock Family Planning Servs. v. Rutledge, 984 F. 3d 682, 688–690 (CA8 2021).

⁵⁸See, e.g., Bristol Regional Women's Center, P.C. v. Slatery, 7 F. 4th 478, 485 (CA6 2021); Reproductive Health Servs. v. Strange, 3 F. 4th 1240, 1269 (CA11 2021) (per curiam); June Medical Servs., L.L.C. v. Gee, 905 F. 3d 787, 814 (CA5 2020), rev'd, 591 U. S. ___; Preterm-Cleveland, 994 F. 3d, at 534; Planned Parenthood of Ark. & Eastern Okla. v. Jegley, 864 F. 3d 953, 958–960 (CA8 2017); McCormack v. Hertzog, 788 F. 3d 1017, 1029–1030 (CA9 2015); compare A Womans Choice-East Side Womens Clinic v. Newman, 305 F. 3d 684, 699 (CA7 2002) (Coffey, J., concurring), with id., at 708 (Wood, J., dissenting).

⁵⁹ See, e.g., Memphis Center for Reproductive Health v. Slatery, 14 F. 4th 409, 451 (CA6 2021) (Thapar, J., concurring in judgment in part and dissenting in part); Preterm-Cleveland, 994 F. 3d, at 524; Planned Parenthood of Ind. & Ky., Inc. v. Commissioner of Ind. State Dept. of

Casey's "undue burden" test has proved to be unworkable. "[P]lucked from nowhere," 505 U. S., at 965 (opinion of Rehnquist, C. J.), it "seems calculated to perpetuate give-ita-try litigation" before judges assigned an unwieldy and inappropriate task. Lehnert v. Ferris Faculty Assn., 500 U. S. 507, 551 (1991) (Scalia, J., concurring in judgment in part and dissenting in part). Continued adherence to that standard would undermine, not advance, the "evenhanded, predictable, and consistent development of legal principles." Payne, 501 U. S., at 827.

D

Effect on other areas of law. Roe and Casey have led to the distortion of many important but unrelated legal doctrines, and that effect provides further support for overruling those decisions. See Ramos, 590 U. S., at ____ (opinion of KAVANAUGH, J.) (slip op., at 8); Janus, 585 U. S., at ____ (slip op., at 34).

Members of this Court have repeatedly lamented that "no legal rule or doctrine is safe from ad hoc nullification by this Court when an occasion for its application arises in a case involving state regulation of abortion." *Thornburgh*, 476 U. S., at 814 (O'Connor, J., dissenting); see *Madsen* v. *Women's Health Center*, *Inc.*, 512 U. S. 753, 785 (1994) (Scalia, J., concurring in judgment in part and dissenting

Health, 888 F. 3d 300, 313 (CA7 2018) (Manion, J., concurring in judgment in part and dissenting in part); Planned Parenthood of Ind. & Ky., Inc. v. Box, 949 F. 3d 997, 999 (CA7 2019) (Easterbrook, J., concurring in denial of reh'g en banc) ("How much burden is 'undue' is a matter of judgment, which depends on what the burden would be . . . and whether that burden is excessive (a matter of weighing costs against benefits, which one judge is apt to do differently from another, and which judges as a group are apt to do differently from state legislators)"); National Abortion Federation v. Gonzales, 437 F. 3d 278, 290–296 (CA2 2006) (Walker, C. J., concurring); Planned Parenthood of Rocky Mountains Servs. Corp. v. Owens, 287 F. 3d 910, 931 (CA10 2002) (Baldock, J., dissenting).

in part); Whole Woman's Health, 579 U.S., at 631–633 (THOMAS, J., dissenting); id., at 645–666, 678–684 (ALITO, J., dissenting); June Medical, 591 U.S., at _____ (GORSUCH, J., dissenting) (slip op., at 1–15).

The Court's abortion cases have diluted the strict standard for facial constitutional challenges. They have ignored the Court's third-party standing doctrine. They have disregarded standard res judicata principles. They have flouted the ordinary rules on the severability of unconstitutional provisions, as well as the rule that statutes should be read where possible to avoid unconstitutionality. And they have distorted First Amendment doctrines.

When vindicating a doctrinal innovation requires courts to engineer exceptions to longstanding background rules, the doctrine "has failed to deliver the 'principled and intelligible' development of the law that *stare decisis* purports to secure." *Id.*, at ____ (THOMAS, J., dissenting) (slip op., at 19) (quoting *Vasquez* v. *Hillery*, 474 U. S. 254, 265 (1986)).

 \mathbf{E}

Reliance interests. We last consider whether overruling *Roe* and *Casey* will upend substantial reliance interests.

⁶⁰ Compare *United States* v. *Salerno*, 481 U. S. 739, 745 (1987), with *Casey*, 505 U. S., at 895; see also *supra*, at 56–59.

⁶¹Compare Warth v. Seldin, 422 U. S. 490, 499 (1975), and Elk Grove Unified School Dist. v. Newdow, 542 U. S. 1, 15, 17–18 (2004), with June Medical, 591 U. S., at ___ (ALITO, J., dissenting) (slip op., at 28), id., at ___ (GORSUCH, J., dissenting) (slip op., at 6–7) (collecting cases), and Whole Woman's Health, 579 U. S., at 632, n. 1 (THOMAS, J., dissenting).

 $^{^{62}}$ Compare id., at 598–606 (majority opinion), with id., at 645–666 (ALITO, J., dissenting).

 $^{^{63}}$ Compare id., at 623–626 (majority opinion), with id., at 644–645 (ALITO, J., dissenting).

 $^{^{64}} See\ Stenberg\ v.\ Carhart, 530\ U.\ S.\ 914, 977–978\ (2000)$ (Kennedy, J., dissenting); id., at 996–997 (Thomas, J., dissenting).

⁶⁵See *Hill* v. *Colorado*, 530 U. S. 703, 741–742 (2000) (Scalia, J., dissenting); *id.*, at 765 (Kennedy, J., dissenting).

See *Ramos*, 590 U. S., at ____ (opinion of KAVANAUGH, J.) (slip op., at 15); *Janus*, 585 U. S., at _____ (slip op., at 34–35).

1

Traditional reliance interests arise "where advance planning of great precision is most obviously a necessity." *Casey*, 505 U. S., at 856 (joint opinion); see also *Payne*, 501 U. S., at 828. In *Casey*, the controlling opinion conceded that those traditional reliance interests were not implicated because getting an abortion is generally "unplanned activity," and "reproductive planning could take virtually immediate account of any sudden restoration of state authority to ban abortions." 505 U. S., at 856. For these reasons, we agree with the *Casey* plurality that conventional, concrete reliance interests are not present here.

2

Unable to find reliance in the conventional sense, the controlling opinion in Casey perceived a more intangible form of reliance. It wrote that "people [had] organized intimate relationships and made choices that define their views of themselves and their places in society . . . in reliance on the availability of abortion in the event that contraception should fail" and that "[t]he ability of women to participate equally in the economic and social life of the Nation has been facilitated by their ability to control their reproductive lives." *Ibid.* But this Court is ill-equipped to assess "generalized assertions about the national psyche." Id., at 957 (opinion of Rehnquist, C. J.). Casey's notion of reliance thus finds little support in our cases, which instead emphasize very concrete reliance interests, like those that develop in "cases involving property and contract rights." Payne, 501 U. S., at 828.

When a concrete reliance interest is asserted, courts are equipped to evaluate the claim, but assessing the novel and

intangible form of reliance endorsed by the *Casey* plurality is another matter. That form of reliance depends on an empirical question that is hard for anyone—and in particular, for a court—to assess, namely, the effect of the abortion right on society and in particular on the lives of women. The contending sides in this case make impassioned and conflicting arguments about the effects of the abortion right on the lives of women. Compare Brief for Petitioners 34– 36; Brief for Women Scholars et al. as Amici Curiae 13–20, 29–41, with Brief for Respondents 36–41; Brief for National Women's Law Center et al. as Amici Curiae 15–32. The contending sides also make conflicting arguments about the status of the fetus. This Court has neither the authority nor the expertise to adjudicate those disputes, and the Casey plurality's speculations and weighing of the relative importance of the fetus and mother represent a departure from the "original constitutional proposition" that "courts do not substitute their social and economic beliefs for the judgment of legislative bodies." Ferguson v. Skrupa, 372 U. S. 726, 729–730 (1963).

Our decision returns the issue of abortion to those legislative bodies, and it allows women on both sides of the abortion issue to seek to affect the legislative process by influencing public opinion, lobbying legislators, voting, and running for office. Women are not without electoral or political power. It is noteworthy that the percentage of women who register to vote and cast ballots is consistently higher than the percentage of men who do so.⁶⁶ In the last election in November 2020, women, who make up around 51.5 percent of the population of Mississippi,⁶⁷ constituted

⁶⁶See Dept. of Commerce, U. S. Census Bureau (Census Bureau), An Analysis of the 2018 Congressional Election 6 (Dec. 2021) (Fig. 5) (showing that women made up over 50 percent of the voting population in every congressional election between 1978 and 2018).

⁶⁷Census Bureau, QuickFacts, Mississippi (July 1, 2021), https://www.

55.5 percent of the voters who cast ballots.⁶⁸

3

Unable to show concrete reliance on *Roe* and *Casey* themselves, the Solicitor General suggests that overruling those decisions would "threaten the Court's precedents holding that the Due Process Clause protects other rights." Brief for United States 26 (citing Obergefell, 576 U.S. 644; Lawrence, 539 U. S. 558; Griswold, 381 U. S. 479). That is not correct for reasons we have already discussed. As even the Casey plurality recognized, "[a]bortion is a unique act" because it terminates "life or potential life." 505 U.S., at 852; see also Roe, 410 U.S., at 159 (abortion is "inherently different from marital intimacy," "marriage," or "procreation"). And to ensure that our decision is not misunderstood or mischaracterized, we emphasize that our decision concerns the constitutional right to abortion and no other right. Nothing in this opinion should be understood to cast doubt on precedents that do not concern abortion.

IV

Having shown that traditional *stare decisis* factors do not weigh in favor of retaining *Roe* or *Casey*, we must address one final argument that featured prominently in the *Casey* plurality opinion.

The argument was cast in different terms, but stated simply, it was essentially as follows. The American people's belief in the rule of law would be shaken if they lost respect for this Court as an institution that decides important cases based on principle, not "social and political pressures." 505 U. S., at 865. There is a special danger that the public will

census.gov/quickfacts/MS.

⁶⁸ Census Bureau, Voting and Registration in the Election of November 2020, Table 4b: Reported Voting and Registration, by Sex, Race and Hispanic Origin, for States: November 2020, https://www.census.gov/data/tables/time-series/demo/voting-and-registration/p20-585.html.

perceive a decision as having been made for unprincipled reasons when the Court overrules a controversial "watershed" decision, such as *Roe*. 505 U. S., at 866–867. A decision overruling *Roe* would be perceived as having been made "under fire" and as a "surrender to political pressure," 505 U. S., at 867, and therefore the preservation of public approval of the Court weighs heavily in favor of retaining *Roe*, see 505 U. S., at 869.

This analysis starts out on the right foot but ultimately veers off course. The Casey plurality was certainly right that it is important for the public to perceive that our decisions are based on principle, and we should make every effort to achieve that objective by issuing opinions that carefully show how a proper understanding of the law leads to the results we reach. But we cannot exceed the scope of our authority under the Constitution, and we cannot allow our decisions to be affected by any extraneous influences such as concern about the public's reaction to our work. Cf. Texas v. Johnson, 491 U.S. 397 (1989); Brown, 347 U.S. 483. That is true both when we initially decide a constitutional issue and when we consider whether to overrule a prior decision. As Chief Justice Rehnquist explained, "The Judicial Branch derives its legitimacy, not from following public opinion, but from deciding by its best lights whether legislative enactments of the popular branches of Government comport with the Constitution. The doctrine of stare decisis is an adjunct of this duty, and should be no more subject to the vagaries of public opinion than is the basic judicial task." Casey, 505 U.S., at 963 (opinion concurring in judgment in part and dissenting in part). In suggesting otherwise, the *Casey* plurality went beyond this Court's role in our constitutional system.

The *Casey* plurality "call[ed] the contending sides of a national controversy to end their national division," and claimed the authority to impose a permanent settlement of the issue of a constitutional abortion right simply by saying

that the matter was closed. Id., at 867. That unprecedented claim exceeded the power vested in us by the Constitution. As Alexander Hamilton famously put it, the Constitution gives the judiciary "neither Force nor Will." The Federalist No. 78, p. 523 (J. Cooke ed. 1961). Our sole authority is to exercise "judgment"—which is to say, the authority to judge what the law means and how it should apply to the case at hand. *Ibid*. The Court has no authority to decree that an erroneous precedent is permanently exempt from evaluation under traditional stare decisis principles. A precedent of this Court is subject to the usual principles of stare decisis under which adherence to precedent is the norm but not an inexorable command. If the rule were otherwise, erroneous decisions like *Plessy* and *Loch*ner would still be the law. That is not how stare decisis operates.

The *Casey* plurality also misjudged the practical limits of this Court's influence. *Roe* certainly did not succeed in ending division on the issue of abortion. On the contrary, *Roe* "inflamed" a national issue that has remained bitterly divisive for the past half century. *Casey*, 505 U. S., at 995 (opinion of Scalia, J.); see also R. Ginsburg, Speaking in a Judicial Voice, 67 N. Y. U. L. Rev. 1185, 1208 (1992) (*Roe* may have "halted a political process," "prolonged divisiveness," and "deferred stable settlement of the issue"). And for the past 30 years, *Casey* has done the same.

Neither decision has ended debate over the issue of a constitutional right to obtain an abortion. Indeed, in this case, 26 States expressly ask us to overrule *Roe* and *Casey* and to return the issue of abortion to the people and their elected representatives. This Court's inability to end debate on the issue should not have been surprising. This Court cannot bring about the permanent resolution of a rancorous national controversy simply by dictating a settlement and telling the people to move on. Whatever influence the Court may have on public attitudes must stem from the

strength of our opinions, not an attempt to exercise "raw judicial power." *Roe*, 410 U.S., at 222 (White, J., dissenting).

We do not pretend to know how our political system or society will respond to today's decision overruling *Roe* and *Casey*. And even if we could foresee what will happen, we would have no authority to let that knowledge influence our decision. We can only do our job, which is to interpret the law, apply longstanding principles of *stare decisis*, and decide this case accordingly.

We therefore hold that the Constitution does not confer a right to abortion. *Roe* and *Casey* must be overruled, and the authority to regulate abortion must be returned to the people and their elected representatives.

V A 1

The dissent argues that we have "abandon[ed]" stare decisis, post, at 30, but we have done no such thing, and it is the dissent's understanding of stare decisis that breaks with tradition. The dissent's foundational contention is that the Court should never (or perhaps almost never) overrule an egregiously wrong constitutional precedent unless the Court can "poin[t] to major legal or factual changes undermining [the] decision's original basis." Post, at 37. To support this contention, the dissent claims that Brown v. Board of Education, 347 U.S. 483, and other landmark cases overruling prior precedents "responded to changed law and to changed facts and attitudes that had taken hold throughout society." Post, at 43. The unmistakable implication of this argument is that only the passage of time and new developments justified those decisions. Recognition that the cases they overruled were egregiously wrong on the day they were handed down was not enough.

The Court has never adopted this strange new version of

stare decisis—and with good reason. Does the dissent really maintain that overruling *Plessy* was not justified until the country had experienced more than a half-century of state-sanctioned segregation and generations of Black school children had suffered all its effects? *Post*, at 44–45.

Here is another example. On the dissent's view, it must have been wrong for West Virginia Bd. of Ed. v. Barnette, 319 U. S. 624, to overrule Minersville School Dist. v. Gobitis, 310 U. S. 586, a bare three years after it was handed down. In both cases, children who were Jehovah's Witnesses refused on religious grounds to salute the flag or recite the pledge of allegiance. The Barnette Court did not claim that its reexamination of the issue was prompted by any intervening legal or factual developments, so if the Court had followed the dissent's new version of stare decisis, it would have been compelled to adhere to Gobitis and countenance continued First Amendment violations for some unspecified period.

Precedents should be respected, but sometimes the Court errs, and occasionally the Court issues an important decision that is egregiously wrong. When that happens, *stare decisis* is not a straitjacket. And indeed, the dissent eventually admits that a decision *could* "be overruled just because it is terribly wrong," though the dissent does not explain when that would be so. *Post*, at 45.

2

Even if the dissent were correct in arguing that an egregiously wrong decision should (almost) never be overruled unless its mistake is later highlighted by "major legal or factual changes," reexamination of *Roe* and *Casey* would be amply justified. We have already mentioned a number of post-*Casey* developments, see *supra*, at 33–34, 59–63, but the most profound change may be the failure of the *Casey* plurality's call for "the contending sides" in the controversy about abortion "to end their national division," 505 U. S., at

867. That has not happened, and there is no reason to think that another decision sticking with *Roe* would achieve what *Casey* could not.

The dissent, however, is undeterred. It contends that the "very controversy surrounding *Roe* and *Casey*" is an important *stare decisis* consideration that requires upholding those precedents. See *post*, at 55–57. The dissent characterizes *Casey* as a "precedent about precedent" that is permanently shielded from further evaluation under traditional *stare decisis* principles. See *post*, at 57. But as we have explained, *Casey* broke new ground when it treated the national controversy provoked by *Roe* as a ground for refusing to reconsider that decision, and no subsequent case has relied on that factor. Our decision today simply applies longstanding *stare decisis* factors instead of applying a version of the doctrine that seems to apply only in abortion cases.

3

Finally, the dissent suggests that our decision calls into question Griswold, Eisenstadt, Lawrence, and Obergefell. Post, at 4–5, 26–27, n. 8. But we have stated unequivocally that "[n]othing in this opinion should be understood to cast doubt on precedents that do not concern abortion." Supra, at 66. We have also explained why that is so: rights regarding contraception and same-sex relationships are inherently different from the right to abortion because the latter (as we have stressed) uniquely involves what *Roe* and *Casey* termed "potential life." Roe, 410 U.S., at 150 (emphasis deleted); Casey, 505 U.S., at 852. Therefore, a right to abortion cannot be justified by a purported analogy to the rights recognized in those other cases or by "appeals to a broader right to autonomy." Supra, at 32. It is hard to see how we could be clearer. Moreover, even putting aside that these cases are distinguishable, there is a further point that the dissent ignores: Each precedent is subject to its own stare

decisis analysis, and the factors that our doctrine instructs us to consider like reliance and workability are different for these cases than for our abortion jurisprudence.

В 1

We now turn to the concurrence in the judgment, which reproves us for deciding whether Roe and Casey should be retained or overruled. That opinion (which for convenience we will call simply "the concurrence") recommends a "more measured course," which it defends based on what it claims is "a straightforward stare decisis analysis." Post, at 1 (opinion of ROBERTS, C. J.). The concurrence would "leave for another day whether to reject any right to an abortion at all," post, at 7, and would hold only that if the Constitution protects any such right, the right ends once women have had "a reasonable opportunity" to obtain an abortion, post, at 1. The concurrence does not specify what period of time is sufficient to provide such an opportunity, but it would hold that 15 weeks, the period allowed under Mississippi's law, is enough—at least "absent rare circumstances." Post, at 2, 10.

There are serious problems with this approach, and it is revealing that nothing like it was recommended by either party. As we have recounted, both parties and the Solicitor General have urged us either to reaffirm or overrule *Roe* and *Casey*. See *supra*, at 4–5. And when the specific approach advanced by the concurrence was broached at oral argument, both respondents and the Solicitor General emphatically rejected it. Respondents' counsel termed it "completely unworkable" and "less principled and less workable than viability." Tr. of Oral Arg. 54. The Solicitor General argued that abandoning the viability line would leave courts and others with "no continued guidance." *Id.*, at 101. What is more, the concurrence has not identified any of the

more than 130 *amicus* briefs filed in this case that advocated its approach. The concurrence would do exactly what it criticizes *Roe* for doing: pulling "out of thin air" a test that "[n]o party or *amicus* asked the Court to adopt." *Post*, at 3.

9

The concurrence's most fundamental defect is its failure to offer any principled basis for its approach. The concurrence would "discar[d]" "the rule from *Roe* and *Casey* that a woman's right to terminate her pregnancy extends up to the point that the fetus is regarded as 'viable' outside the womb." *Post*, at 2. But this rule was a critical component of the holdings in *Roe* and *Casey*, and *stare decisis* is "a doctrine of preservation, not transformation," *Citizens United* v. *Federal Election Comm'n*, 558 U. S. 310, 384 (2010) (ROBERTS, C. J., concurring). Therefore, a new rule that discards the viability rule cannot be defended on *stare decisis* grounds.

The concurrence concedes that its approach would "not be available" if "the rationale of *Roe* and *Casey* were inextricably entangled with and dependent upon the viability standard." *Post*, at 7. But the concurrence asserts that the viability line is separable from the constitutional right they recognized, and can therefore be "discarded" without disturbing any past precedent. *Post*, at 7–8. That is simply incorrect.

Roe's trimester rule was expressly tied to viability, see 410 U. S., at 163–164, and viability played a critical role in later abortion decisions. For example, in *Planned Parenthood of Central Mo.* v. *Danforth*, 428 U. S. 52, the Court reiterated *Roe*'s rule that a "State may regulate an abortion to protect the life of the fetus and even may proscribe abortion" at "the stage *subsequent to viability*." 428 U. S., at 61 (emphasis added). The Court then rejected a challenge to Missouri's definition of viability, holding that the State's definition was consistent with *Roe*'s. 428 U. S.,

at 63–64. If viability was not an essential part of the rule adopted in *Roe*, the Court would have had no need to make that comparison.

The holding in *Colautti* v. *Franklin*, 439 U. S. 379, is even more instructive. In that case, the Court noted that prior cases had "stressed viability" and reiterated that "[v]iability is the critical point" under *Roe.* 439 U. S., at 388–389. It then struck down Pennsylvania's definition of viability, *id.*, at 389–394, and it is hard to see how the Court could have done that if *Roe*'s discussion of viability was not part of its holding.

When the Court reconsidered *Roe* in *Casey*, it left no doubt about the importance of the viability rule. It described the rule as *Roe*'s "central holding," 505 U. S., at 860, and repeatedly stated that the right it reaffirmed was "the right of the woman to choose to have an abortion *before viability*." *Id.*, at 846 (emphasis added). See *id.*, at 871 ("The woman's right to terminate her pregnancy *before viability* is the most central principle of *Roe* v. *Wade*. It is a rule of law and a component of liberty we cannot renounce" (emphasis added)); *id.*, at 872 (A "woman has a right to choose to terminate or continue her pregnancy *before viability*" (emphasis added)); *id.*, at 879 ("[A] State may not prohibit any woman from making the ultimate decision to terminate her pregnancy *before viability*" (emphasis added)).

Our subsequent cases have continued to recognize the centrality of the viability rule. See *Whole Women's Health*, 579 U. S., at 589–590 ("[A] provision of law is constitutionally invalid, if the 'purpose or effect' of the provision 'is to place a substantial obstacle in the path of a woman seeking an abortion *before the fetus attains viability*" (emphasis deleted and added)); *id.*, at 627 ("[W]e now use 'viability' as the relevant point at which a State may begin limiting women's access to abortion for reasons unrelated to maternal health" (emphasis added)).

Not only is the new rule proposed by the concurrence inconsistent with *Casey*'s unambiguous "language," *post*, at 8, it is also contrary to the judgment in that case and later abortion cases. In *Casey*, the Court held that Pennsylvania's spousal-notification provision was facially unconstitutional, not just that it was unconstitutional as applied to abortions sought prior to the time when a woman has had a reasonable opportunity to choose. See 505 U. S., at 887–898. The same is true of *Whole Women's Health*, which held that certain rules that required physicians performing abortions to have admitting privileges at a nearby hospital were facially unconstitutional because they placed "a substantial obstacle in the path of women seeking *a previability abortion*." 579 U. S., at 591 (emphasis added).

For all these reasons, stare decisis cannot justify the new "reasonable opportunity" rule propounded by the concurrence. If that rule is to become the law of the land, it must stand on its own, but the concurrence makes no attempt to show that this rule represents a correct interpretation of the Constitution. The concurrence does not claim that the right to a reasonable opportunity to obtain an abortion is "'deeply rooted in this Nation's history and tradition" and "implicit in the concept of ordered liberty." Glucksberg, 521 U.S., at 720–721. Nor does it propound any other theory that could show that the Constitution supports its new rule. And if the Constitution protects a woman's right to obtain an abortion, the opinion does not explain why that right should end after the point at which all "reasonable" women will have decided whether to seek an abortion. While the concurrence is moved by a desire for judicial minimalism, "we cannot embrace a narrow ground of decision simply because it is narrow; it must also be right." *Citizens* United, 558 U.S., at 375 (ROBERTS, C.J., concurring). For the reasons that we have explained, the concurrence's approach is not.

3

The concurrence would "leave for another day whether to reject any right to an abortion at all," post, at 7, but "another day" would not be long in coming. Some States have set deadlines for obtaining an abortion that are shorter than Mississippi's. See, e.g., Memphis Center for Reproductive Health v. Slatery, 14 F. 4th, at 414 (considering law with bans "at cascading intervals of two to three weeks" beginning at six weeks), reh'g en banc granted, 14 F. 4th 550 (CA6 2021). If we held only that Mississippi's 15-week rule is constitutional, we would soon be called upon to pass on the constitutionality of a panoply of laws with shorter deadlines or no deadline at all. The "measured course" charted by the concurrence would be fraught with turmoil until the Court answered the question that the concurrence seeks to defer.

Even if the Court ultimately adopted the new rule suggested by the concurrence, we would be faced with the difficult problem of spelling out what it means. For example, if the period required to give women a "reasonable" opportunity to obtain an abortion were pegged, as the concurrence seems to suggest, at the point when a certain percentage of women make that choice, see *post*, at 1–2, 9–10, we would have to identify the relevant percentage. It would also be necessary to explain what the concurrence means when it refers to "rare circumstances" that might justify an exception. *Post*, at 10. And if this new right aims to give women a reasonable opportunity to get an abortion, it would be necessary to decide whether factors other than promptness in deciding might have a bearing on whether such an opportunity was available.

In sum, the concurrence's quest for a middle way would only put off the day when we would be forced to confront the question we now decide. The turmoil wrought by *Roe* and *Casey* would be prolonged. It is far better—for this Court

and the country—to face up to the real issue without further delay.

VI

We must now decide what standard will govern if state abortion regulations undergo constitutional challenge and whether the law before us satisfies the appropriate standard.

Α

Under our precedents, rational-basis review is the appropriate standard for such challenges. As we have explained, procuring an abortion is not a fundamental constitutional right because such a right has no basis in the Constitution's text or in our Nation's history. See *supra*, at 8–39.

It follows that the States may regulate abortion for legitimate reasons, and when such regulations are challenged under the Constitution, courts cannot "substitute their social and economic beliefs for the judgment of legislative bodies." Ferguson, 372 U. S., at 729–730; see also Dandridge v. Williams, 397 U. S. 471, 484–486 (1970); United States v. Carolene Products Co., 304 U. S. 144, 152 (1938). That respect for a legislature's judgment applies even when the laws at issue concern matters of great social significance and moral substance. See, e.g., Board of Trustees of Univ. of Ala. v. Garrett, 531 U. S. 356, 365–368 (2001) ("treatment of the disabled"); Glucksberg, 521 U. S., at 728 ("assisted suicide"); San Antonio Independent School Dist. v. Rodriguez, 411 U. S. 1, 32–35, 55 (1973) ("financing public education").

A law regulating abortion, like other health and welfare laws, is entitled to a "strong presumption of validity." *Heller* v. *Doe*, 509 U. S. 312, 319 (1993). It must be sustained if there is a rational basis on which the legislature could have thought that it would serve legitimate state interests. *Id.*, at 320; *FCC* v. *Beach Communications*, *Inc.*, 508 U. S.

307, 313 (1993); New Orleans v. Dukes, 427 U. S. 297, 303 (1976) (per curiam); Williamson v. Lee Optical of Okla., Inc., 348 U. S. 483, 491 (1955). These legitimate interests include respect for and preservation of prenatal life at all stages of development, Gonzales, 550 U. S., at 157–158; the protection of maternal health and safety; the elimination of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical profession; the mitigation of fetal pain; and the prevention of discrimination on the basis of race, sex, or disability. See id., at 156–157; Roe, 410 U. S., at 150; cf. Glucksberg, 521 U. S., at 728–731 (identifying similar interests).

P

These legitimate interests justify Mississippi's Gestational Age Act. Except "in a medical emergency or in the case of a severe fetal abnormality," the statute prohibits abortion "if the probable gestational age of the unborn human being has been determined to be greater than fifteen (15) weeks." Miss. Code Ann. §41–41–191(4)(b). The Mississippi Legislature's findings recount the stages of "human prenatal development" and assert the State's interest in "protecting the life of the unborn." §2(b)(i). The legislature also found that abortions performed after 15 weeks typically use the dilation and evacuation procedure, and the legislature found the use of this procedure "for nontherapeutic or elective reasons [to be] a barbaric practice, dangerous for the maternal patient, and demeaning to the medical profession." §2(b)(i)(8); see also Gonzales, 550 U.S., at 135–143 (describing such procedures). These legitimate interests provide a rational basis for the Gestational Age Act, and it follows that respondents' constitutional challenge must fail.

VII

We end this opinion where we began. Abortion presents

a profound moral question. The Constitution does not prohibit the citizens of each State from regulating or prohibiting abortion. *Roe* and *Casey* arrogated that authority. We now overrule those decisions and return that authority to the people and their elected representatives.

The judgment of the Fifth Circuit is reversed, and the case is remanded for further proceedings consistent with this opinion.

It is so ordered.

APPENDICES

Α

This appendix contains statutes criminalizing abortion at all stages of pregnancy in the States existing in 1868. The statutes appear in chronological order.

1. Missouri (1825):

Sec. 12. "That every person who shall wilfully and maliciously administer or cause to be administered to or taken by any person, any poison, or other noxious, poisonous or destructive substance or liquid, with an intention to harm him or her thereby to murder, or thereby to cause or procure the miscarriage of any woman then being with child, and shall thereof be duly convicted, shall suffer imprisonment not exceeding seven years, and be fined not exceeding three thousand dollars." 69

2. Illinois (1827):

Sec. 46. "Every person who shall wilfully and maliciously administer, or cause to be administered to, or taken by any person, any poison, or other noxious or

⁶⁹ 1825 Mo. Laws p. 283 (emphasis added); see also, Mo. Rev. Stat., Art. II, §§10, 36 (1835) (extending liability to abortions performed by instrument and establishing differential penalties for pre- and post-quickening abortion) (emphasis added).

destructive substance or liquid, with an intention to cause the death of such person, or to procure the miscarriage of any woman, then being with child, and shall thereof be duly convicted, shall be imprisoned for a term not exceeding three years, and be fined in a sum not exceeding one thousand dollars." ⁷⁰

3. New York (1828):

Sec. 9. "Every person who shall administer to any woman pregnant with a quick child, any medicine, drug or substance whatever, or shall use or employ any instrument or other means, with intent thereby to destroy such child, unless the same shall have been necessary to preserve the life of such mother, or shall have been advised by two physicians to be necessary for such purpose, shall, in case the death of such child or of such mother be thereby produced, be deemed guilty of manslaughter in the second degree."

Sec. 21. "Every person who shall willfully administer to any pregnant woman, any medicine, drug, substance or thing whatever, or shall use or employ any instrument of other means whatever, with intent thereby to procure the miscarriage of any such woman, unless the same shall have been necessary to preserve the life of such woman, or shall have been advised by two physicians to be necessary for that purpose; shall, upon conviction, be punished by imprisonment in a county jail not more than one year, or by fine not exceeding five hundred dollars, or by both such fine and imprisonment."

⁷⁰ Ill. Rev. Code §46 (1827) (emphasis added); see also Ill. Rev. Code §46 (1833) (same); 1867 Ill. Laws p. 89 (extending liability to abortions "by means of any instrument[s]" and raising penalties to imprisonment "not less than two nor more than ten years").

⁷¹N. Y. Rev. Stat., pt. 4, ch. 1, Tit. 2, §9 (emphasis added); Tit. 6, §21

4. Ohio (1834):

Sec. 1. "Be it enacted by the General Assembly of State of Ohio, That any physician, or other person, who shall wilfully administer to any pregnant woman any medicine, drug, substance, or thing whatever, or shall use any instrument or other means whatever, with intent thereby to procure the miscarriage of any such woman, unless the same shall have been necessary to preserve the life of such woman, or shall have been advised by two physicians to be necessary for that purpose, shall, upon conviction, be punished by imprisonment in the county jail not more than one year, or by fine not exceeding five hundred dollars, or by both such fine and imprisonment."

Sec. 2. "That any physician, or other person, who shall administer to any woman pregnant with a quick child, any medicine, drug, or substance whatever, or shall use or employ any instrument, or other means, with intent thereby to destroy such child, unless the same shall have been necessary to preserve the life of such mother, or shall have been advised by two physicians to be necessary for such purpose, shall, in case of the death of such child or mother in consequence thereof, be deemed guilty of high misdemeanor, and, upon conviction thereof, shall be imprisoned in the penitentiary not more than seven years, nor less than one year."⁷²

5. Indiana (1835):

Sec. 3. "That every person who shall wilfully administer to any pregnant woman, any medicine, drug, substance or thing whatever, or shall use or employ any instrument or other means whatever, with intent

^{(1828) (}emphasis added); 1829 N. Y. Laws p. 19 (codifying these provisions in the revised statutes).

⁷² 1834 Ohio Laws pp. 20–21 (emphasis deleted and added).

thereby to procure the miscarriage of any such woman, unless the same shall have been necessary to preserve the life of such woman, shall upon conviction be punished by imprisonment in the county jail any term of [time] not exceeding twelve months and be fined any sum not exceeding five hundred dollars."⁷³

6. Maine (1840):

Sec. 13. "Every person, who shall administer to any woman pregnant with child, whether such child be quick or not, any medicine, drug or substance whatever, or shall use or employ any instrument or other means whatever, with intent to destroy such child, and shall thereby destroy such child before its birth, unless the same shall have been done as necessary to preserve the life of the mother, shall be punished by imprisonment in the state prison, not more than five years, or by fine, not exceeding one thousand dollars, and imprisonment in the county jail, not more than one year."

Sec. 14. "Every person, who shall administer to any woman, pregnant with child, whether such child shall be quick or not, any medicine, drug or substance whatever, or shall use or employ any instrument or other means whatever, with intent thereby to procure the miscarriage of such woman, unless the same shall have been done, as necessary to preserve her life, shall be punished by imprisonment in the county jail, not more than one year, or by fine, not exceeding one thousand dollars."⁷⁴

7. Alabama (1841):

Sec. 2. "Every person who shall wilfully administer to any pregnant woman any medicines, drugs, substance or thing whatever, or shall use and employ any

⁷³ 1835 Ind. Laws p. 66 (emphasis added).

⁷⁴Me. Rev. Stat., Tit. 12, ch. 160, §§13–14 (1840) (emphasis added).

instrument or means whatever with intent thereby to procure the miscarriage of such woman, unless the same shall be necessary to preserve her life, or shall have been advised by a respectable physician to be necessary for that purpose, shall upon conviction, be punished by fine not exceeding five hundred dollars, and by imprisonment in the county jail, not less than three, and not exceeding six months."75

8. Massachusetts (1845):

Ch. 27. "Whoever, maliciously or without lawful justification, with intent to cause and procure the miscarriage of a woman then pregnant with child, shall administer to her, prescribe for her, or advise or direct her to take or swallow, any poison, drug, medicine or noxious thing, or shall cause or procure her with like intent, to take or swallow any poison, drug, medicine or noxious thing; and whoever maliciously and without lawful justification, shall use any instrument or means whatever with the like intent, and every person, with the like intent, knowingly aiding and assisting such offender or offenders, shall be deemed guilty of felony, if the woman die in consequence thereof, and shall be imprisoned not more than twenty years, nor less than five years in the State Prison; and if the woman doth not die in consequence thereof, such offender shall be guilty of a misdemeanor, and shall be punished by imprisonment not exceeding seven years, nor less than one year, in the state prison or house of correction, or common jail, and by fine not exceeding two thousand dollars."76

9. Michigan (1846):

Sec. 33. "Every person who shall administer to any

⁷⁵ 1841 Ala. Acts p. 143 (emphasis added).

⁷⁶ 1845 Mass. Acts p. 406 (emphasis added).

woman pregnant with a quick child, any medicine, drug or substance whatever, or shall use or employ any instrument or other means, with intent thereby to destroy such child, unless the same shall have been necessary to preserve the life of such mother, or shall have been advised by two physicians to be necessary for such purpose, shall, in case the death of such child or of such mother be thereby produced, be deemed guilty of manslaughter."

Sec. 34. "Every person who shall wilfully administer to any pregnant woman any medicine, drug, substance or thing whatever, or shall employ any instrument or other means whatever, with intent thereby to procure the miscarriage of any such woman, unless the same shall have been necessary to preserve the life of such woman, or shall have been advised by two physicians to be necessary for that purpose, shall, upon conviction, be punished by imprisonment in a county jail not more than one year, or by a fine not exceeding five hundred dollars, or by both such fine and imprisonment."⁷⁷

10. Vermont (1846):

Sec. 1. "Whoever maliciously, or without lawful justification with intent to cause and procure the miscarriage of a woman, then pregnant with child, shall administer to her, prescribe for her, or advise or direct her to take or swallow any poison, drug, medicine or noxious thing, or shall cause or procure her, with like intent, to take or swallow any poison, drug, medicine or noxious thing, and whoever maliciously and without lawful justification, shall use any instrument or means whatever, with the like intent, and every person, with the like intent, knowingly aiding and assisting such offenders, shall be deemed guilty of felony, if the woman die in consequence thereof, and shall be imprisoned in

⁷⁷Mich. Rev. Stat., Tit. 30, ch. 153, §§33–34 (1846) (emphasis added).

the state prison, not more than ten years, nor less than five years; and if the woman does not die in consequence thereof, such offenders shall be deemed guilty of a misdemeanor; and shall be punished by imprisonment in the state prison not exceeding three years, nor less than one year, and pay a fine not exceeding two hundred dollars."⁷⁸

11. Virginia (1848):

Sec. 9. "Any free person who shall administer to any pregnant woman, any medicine, drug or substance whatever, or use or employ any instrument or other means with intent thereby to destroy the child with which such woman may be pregnant, or to produce abortion or miscarriage, and shall thereby destroy such child, or produce such abortion or miscarriage, unless the same shall have been done to preserve the life of such woman, shall be punished, if the death of a quick child be thereby produced, by confinement in the penitentiary, for not less than one nor more than five years, or if the death of a child, not quick, be thereby produced, by confinement in the jail for not less than one nor more than twelve months." ⁷⁹

12. New Hampshire (1849):

Sec. 1. "That every person, who shall wilfully administer to any pregnant woman, any medicine, drug, substance or thing whatever, or shall use or employ any instrument or means whatever with intent thereby to procure the miscarriage of any such woman, unless the same shall have been necessary to preserve the life of such woman, or shall have been advised by two physicians to be necessary for that purpose, shall, upon conviction, be punished by imprisonment in the county jail

⁷⁸ 1846 Vt. Acts & Resolves pp. 34–35 (emphasis added).

⁷⁹ 1848 Va. Acts p. 96 (emphasis added).

not more than one year, or by a fine not exceeding one thousand dollars, or by both such fine and imprisonment at the discretion of the Court."

Sec. 2. "Every person who shall administer to any woman pregnant with a quick child, any medicine, drug or substance whatever, or shall use or employ any instrument or means whatever, with intent thereby to destroy such child, unless the same shall have been necessary to preserve the life of such woman, or shall have been advised by two physicians to be necessary for such purpose, shall, upon conviction, be punished by fine not exceeding one thousand dollars, and by confinement to hard labor not less than one year, nor more than ten years."80

13. New Jersey (1849):

"That if any person or persons, maliciously or without lawful justification, with intent to cause and procure the miscarriage of a woman then pregnant with child, shall administer to her, prescribe for her, or advise or direct her to take or swallow any poison, drug, medicine, or noxious thing; and if any person or persons maliciously, and without lawful justification, shall use any instrument or means whatever, with the like intent; and every person, with the like intent, knowingly aiding and assisting such offender or offenders, shall, on conviction thereof, be adjudged guilty of a high misdemeanor; and if the woman die in consequence thereof, shall be punished by fine, not exceeding one thousand dollars, or imprisonment at hard labour for any term not exceeding fifteen years, or both; and if the woman doth not die in consequence thereof, such offender shall, on conviction thereof, be adjudged guilty of a misdemeanor, and be punished by fine, not exceed-

^{80 1849} N. H. Laws p. 708 (emphasis added).

ing five hundred dollars, or imprisonment at hard labour, for any term not exceeding seven years, or both."81

14. California (1850):

Sec. 45. "And every person who shall administer or cause to be administered or taken, any medical substances, or shall use or cause to be used any instruments whatever, with the intention to procure the miscarriage of any woman then being with child, and shall be thereof duly convicted, shall be punished by imprisonment in the State Prison for a term not less than two years, nor more than five years: Provided, that no physician shall be affected by the last clause of this section, who, in the discharge of his professional duties, deems it necessary to produce the miscarriage of any woman in order to save her life."82

15. Texas (1854):

Sec. 1. "If any person, with the intent to procure the miscarriage of any woman being with child, unlawfully and maliciously shall administer to her or cause to be taken by her any poison or other noxious thing, or shall use any instrument or any means whatever, with like intent, every such offender, and every person counselling or aiding or abetting such offender, shall be punished by confinement to hard labor in the Penitentiary not exceeding ten years." 83

16. Louisiana (1856):

Sec. 24. "Whoever shall feloniously administer or cause to be administered any drug, potion, or any other thing to any woman, for the purpose of procuring a premature delivery, and whoever shall administer or

^{81 1849} N. J. Laws pp. 266–267 (emphasis added).

^{82 1850} Cal. Stats. p. 233 (emphasis added and deleted).

^{83 1854} Tex. Gen. Laws p. 58 (emphasis added).

cause to be administered to any woman pregnant with child, any drug, potion, or any other thing, for the purpose of procuring abortion, or a premature delivery, shall be imprisoned at hard labor, for not less than one, nor more than ten years."84

17. Iowa (1858):

Sec. 1. "That every person who shall willfully administer to any pregnant woman, any medicine, drug, substance or thing whatever, or shall use or employ any instrument or other means whatever, with the intent thereby to procure the miscarriage of any such woman, unless the same shall be necessary to preserve the life of such woman, shall upon conviction thereof, be punished by imprisonment in the county jail for a term of not exceeding one year, and be fined in a sum not exceeding one thousand dollars."

18. Wisconsin (1858):

Sec. 11. "Every person who shall administer to any woman pregnant with a child any medicine, drug, or substance whatever, or shall use or employ any instrument or other means, with intent thereby to destroy such child, unless the same shall have been necessary to preserve the life of such mother, or shall have been advised by two physicians to be necessary for such purpose, shall, in case the death of such child or of such mother be thereby produced, be deemed guilty of manslaughter in the second degree." 86

Sec. 58. "Every person who shall administer to any pregnant woman, or prescribe for any such woman, or advise or procure any such woman to take, any medicine, drug, or substance or thing whatever, or shall use

⁸⁴ La. Rev. Stat. §24 (1856) (emphasis added).

 $^{^{85}1858}$ Iowa Acts p. 93 (codified in Iowa Rev. Laws $\S4221)$ (emphasis added).

⁸⁶ Wis. Rev. Stat., ch. 164, §11, ch. 169, §58 (1858) (emphasis added).

or employ any instrument or other means whatever, or advise or procure the same to be used, with intent thereby to procure the miscarriage of any such woman, shall upon conviction be punished by imprisonment in a county jail, not more than one year nor less than three months, or by fine, not exceeding five hundred dollars, or by both fine and imprisonment, at the discretion of the court."

19. Kansas (1859):

Sec. 10. "Every person who shall administer to any woman, pregnant with a quick child, any medicine, drug or substance whatsoever, or shall use or employ any instrument or other means, with intent thereby to destroy such child, unless the same shall have been necessary to preserve the life of such mother, or shall have been advised by a physician to be necessary for that purpose, shall be deemed guilty of manslaughter in the second degree."

Sec. 37. "Every physician or other person who shall wilfully administer to any pregnant woman any medicine, drug or substance whatsoever, or shall use or employ any instrument or means whatsoever, with intent thereby to procure abortion or the miscarriage of any such woman, unless the same shall have been necessary to preserve the life of such woman, or shall have been advised by a physician to be necessary for that purpose, shall, upon conviction, be adjudged guilty of a misdemeanor, and punished by imprisonment in a county jail not exceeding one year, or by fine not exceeding five hundred dollars, or by both such fine and imprisonment." 87

20. Connecticut (1860):

Sec. 1. "That any person with intent to procure the

⁸⁷ 1859 Kan. Laws pp. 233, 237 (emphasis added).

miscarriage or abortion of any woman, shall give or administer to her, prescribe for her, or advise, or direct, or cause or procure her to take, any medicine, drug or substance whatever, or use or advise the use of any instrument, or other means whatever, with the like intent, unless the same shall have been necessary to preserve the life of such woman, or of her unborn child, shall be deemed guilty of felony, and upon due conviction thereof shall be punished by imprisonment in the Connecticut state prison, not more than five years or less than one year, or by a fine of one thousand dollars, or both, at the discretion of the court."88

21. Pennsylvania (1860):

Sec. 87. "If any person shall unlawfully administer to any woman, pregnant or quick with child, or supposed and believed to be pregnant or quick with child, any drug, poison, or other substance whatsoever, or shall unlawfully use any instrument or other means whatsoever, with the intent to procure the miscarriage of such woman, and such woman, or any child with which she may be quick, shall die in consequence of either of said unlawful acts, the person so offending shall be guilty of felony, and shall be sentenced to pay a fine not exceeding five hundred dollars, and to undergo an imprisonment, by separate or solitary confinement at labor, not exceeding seven years."

Sec. 88. "If any person, with intent to procure the miscarriage of any woman, shall unlawfully administer to her any poison, drug or substance whatsoever, or shall unlawfully use any instrument, or other means whatsoever, with the like intent, such person shall be guilty of felony, and being thereof convicted, shall be sentenced to pay a fine not exceeding five hundred dol-

^{88 1860} Conn. Pub. Acts p. 65 (emphasis added).

lars, and undergo an imprisonment, by separate or solitary confinement at labor, not exceeding three years."89

22. Rhode Island (1861):

Sec. 1. "Every person who shall be convicted of wilfully administering to any pregnant woman, or to any woman supposed by such person to be pregnant, anything whatever, or shall employ any means whatever, with intent thereby to procure the miscarriage of such woman, unless the same is necessary to preserve her life, shall be imprisoned not exceeding one year, or fined not exceeding one thousand dollars." ⁹⁰

23. Nevada (1861):

Sec. 42. "[E]very person who shall administer, or cause to be administered or taken, any medicinal substance, or shall use, or cause to be used, any instruments whatever, with the intention to procure the miscarriage of any woman then being with child, and shall be thereof duly convicted, shall be punished by imprisonment in the Territorial prison, for a term not less than two years, nor more than five years; provided, that no physician shall be affected by the last clause of this section, who, in the discharge of his professional duties, deems it necessary to produce the miscarriage of any woman in order to save her life."91

24. West Virginia (1863):

West Virginia's Constitution adopted the laws of Virginia when it became its own State:

"Such parts of the common law and of the laws of the State of Virginia as are in force within the boundaries

^{89 1861} Pa. Laws pp. 404–405 (emphasis added).

⁹⁰R. I. Acts & Resolves p. 133 (emphasis added).

^{91 1861} Nev. Laws p. 63 (emphasis added and deleted).

of the State of West Virginia, when this Constitution goes into operation, and are not repugnant thereto, shall be and continue the law of this State until altered or repealed by the Legislature."⁹²

The Virginia law in force in 1863 stated:

Sec. 8. "Any free person who shall administer to, or cause to be taken, *by a woman*, any drug or other thing, or use any means, with intent to destroy her unborn child, or to produce abortion or miscarriage, and shall thereby destroy such child, or produce such abortion or miscarriage, shall be confined in the penitentiary not less than one, nor more than five years. No person, by reason of any act mentioned in this section, shall be punishable where such act is done in good faith, with the intention of saving the life of such woman or child."93

25. Oregon (1864):

Sec. 509. "If any person shall administer to any woman pregnant with child, any medicine, drug or substance whatever, or shall use or employ any instrument or other means, with intent thereby to destroy such child, unless the same shall be necessary to preserve the life of such mother, such person shall, in case the death of such child or mother be thereby produced, be deemed guilty of manslaughter."

26. Nebraska (1866):

Sec. 42. "Every person who shall willfully and maliciously administer or cause to be administered to or taken by any person, any poison or other noxious or destructive substance or liquid, with the intention to

⁹² W. Va. Const., Art. XI, §8 (1862).

⁹³ Va. Code, Tit. 54, ch. 191, §8 (1849) (emphasis added); see also W. Va. Code, ch. 144, §8 (1870) (similar).

⁹⁴ Ore. Gen. Laws, Crim. Code, ch. 43, §509 (1865).

cause the death of such person, and being thereof duly convicted, shall be punished by confinement in the penitentiary for a term not less than one year and not more than seven years. And every person who shall administer or cause to be administered or taken, any such poison, substance or liquid, with the intention to procure the miscarriage of any woman then being with child, and shall thereof be duly convicted, shall be imprisoned for a term not exceeding three years in the penitentiary, and fined in a sum not exceeding one thousand dollars."

27. Maryland (1868):

Sec. 2. "And be it enacted, That any person who shall knowingly advertise, print, publish, distribute or circulate, or knowingly cause to be advertised, printed, published, distributed or circulated, any pamphlet, printed paper, book, newspaper notice, advertisement or reference containing words or language, giving or conveying any notice, hint or reference to any person, or to the name of any person real or fictitious, from whom; or to any place, house, shop or office, when any poison, drug, mixture, preparation, medicine or noxious thing, or any instrument or means whatever; for the purpose of producing abortion, or who shall knowingly sell, or cause to be sold any such poison, drug, mixture, preparation, medicine or noxious thing or instrument of any kind whatever; or where any advice, direction, information or knowledge may be obtained for the purpose of causing the miscarriage or abortion of any woman pregnant with child, at any period of her pregnancy, or shall knowingly sell or cause to be sold any medicine, or who shall knowingly use or cause to be used any means

⁹⁵Neb. Rev. Stat., Tit. 4, ch. 4, §42 (1866) (emphasis added); see also Neb. Gen. Stat., ch. 58, §§6, 39 (1873) (expanding criminal liability for abortions by other means, including instruments).

whatsoever for that purpose, shall be punished by imprisonment in the penitentiary for not less than three years, or by a fine of not less than five hundred nor more than one thousand dollars, or by both, in the discretion of the Court; and in case of fine being imposed, one half thereof shall be paid to the State of Maryland, and one-half to the School Fund of the city or county where the offence was committed; provided, however, that nothing herein contained shall be construed so as to prohibit the supervision and management by a regular practitioner of medicine of all cases of abortion occurring spontaneously, either as the result of accident, constitutional debility, or any other natural cause, or the production of abortion by a regular practitioner of medicine when, after consulting with one or more respectable physicians, he shall be satisfied that the foetus is dead, or that no other method will secure the safety of the mother."96

28. Florida (1868):

Ch. 3, Sec. 11. "Every person who shall administer to any woman pregnant with a quick child any medicine, drug, or substance whatever, or shall use or employ any instrument, or other means, with intent thereby to destroy such child, unless the same shall have been necessary to preserve the life of such mother, or shall have been advised by two physicians to be necessary for such purpose, shall, in case the death of such child or of such mother be thereby produced, be deemed guilty of manslaughter in the second degree."

Ch. 8, Sec. 9. "Whoever, with intent to procure miscarriage of any woman, unlawfully administers to her, or advises, or prescribes for her, or causes to be taken by her, any poison, drug, medicine, or other noxious thing, or unlawfully uses any instrument or other

⁹⁶ 1868 Md. Laws p. 315 (emphasis deleted and added).

means whatever with the like intent, or with like intent aids or assists therein, shall, if the woman does not die in consequence thereof, be punished by imprisonment in the State penittentiary not exceeding seven years, nor less than one year, or by fine not exceeding one thousand dollars."⁹⁷

29. Minnesota (1873):

Sec. 1. "That any person who shall administer to any woman with child, or prescribe for any such woman, or suggest to, or advise, or procure her to take any medicine, drug, substance or thing whatever, or who shall use or employ, or advise or suggest the use or employment of any instrument or other means or force whatever, with intent thereby to cause or procure the miscarriage or abortion or premature labor of any such woman, unless the same shall have been necessary to preserve her life, or the life of such child, shall, in case the death of such child or of such woman results in whole or in part therefrom, be deemed guilty of a felony, and upon conviction thereof, shall be punished by imprisonment in the state prison for a term not more than ten (10) years nor less than three (3) years."

Sec. 2. "Any person who shall administer to any woman with child, or prescribe, or procure, or provide for any such woman, or suggest to, or advise, or procure any such woman to take any medicine, drug, substance or thing whatever, or shall use or employ, or suggest, or advise the use or employment of any instrument or other means or force whatever, with intent thereby to cause or procure the miscarriage or abortion or premature labor of any such woman, shall upon conviction thereof be punished by imprisonment in the state prison for a term not more than two years nor less than

^{97 1868} Fla. Laws, ch. 1637, pp. 64, 97 (emphasis added).

one year, or by fine not more than five thousand dollars nor less than five hundred dollars, or by such fine and imprisonment both, at the discretion of the court."98

30. Arkansas (1875):

Sec. 1. "That it shall be unlawful for any one to administer or prescribe any medicine or drugs to any woman with child, with intent to produce an abortion, or premature delivery of any foetus before the period of quickening, or to produce or attempt to produce such abortion by any other means; and any person offending against the provision of this section, shall be fined in any sum not exceeding one thousand (\$1000) dollars, and imprisoned in the penitentiary not less than one (1) nor more than five (5) years; provided, that this section shall not apply to any abortion produced by any regular practicing physician, for the purpose of saving the mother's life." ⁹⁹

31. Georgia (1876):

Sec. 2. "That every person who shall administer to any woman pregnant with a child, any medicine, drug, or substance whatever, or shall use or employ any instrument or other means, with intent thereby to destroy such child, unless the same shall have been necessary to preserve the life of such mother, or shall have been advised by two physicians to be necessary for such purpose, shall, in case the death of such child or mother be thereby produced, be declared guilty of an assault with intent to murder."

Sec. 3. "That any person who shall wilfully administer to any pregnant woman any medicine, drug or substance, or anything whatever, or shall employ any instrument or means whatever, with intent thereby to

⁹⁸ 1873 Minn. Laws pp. 117-118 (emphasis added).

^{99 1875} Ark. Acts p. 5 (emphasis added and deleted).

procure the miscarriage or abortion of any such woman, unless the same shall have been necessary to preserve the life of such woman, or shall have been advised by two physicians to be necessary for that purpose, shall, upon conviction, be punished as prescribed in section 4310 of the Revised Code of Georgia."¹⁰⁰

32. North Carolina (1881):

Sec. 1. "That every person who shall wilfully administer to any woman either pregnant or quick with child, or prescribe for any such woman, or advise or procure any such woman to take any medicine, drug or substance whatever, or shall use or employ any instrument or other means with intent thereby to destroy said child, unless the same shall have been necessary to preserve the life of such mother, shall be guilty of a felony, and shall be imprisoned in the state penitentiary for not less than one year nor more than ten years, and be fined at the discretion of the court."

Sec. 2. "That every person who shall administer to any pregnant woman, or prescribe for any such woman, or advise and procure such woman to take any medicine, drug or any thing whatsoever, with intent thereby to procure the miscarriage of any such woman, or to injure or destroy such woman, or shall use any instrument or application for any of the above purposes, shall be guilty of a misdemeanor, and, on conviction, shall be imprisoned in the jail or state penitentiary for not less than one year or more than five years, and fined at the discretion of the court." ¹⁰¹

33. Delaware (1883):

Sec. 2. "Every person who, with the intent to procure

¹⁰⁰ 1876 Ga. Acts & Resolutions p. 113 (emphasis added).

¹⁰¹ 1881 N. C. Sess. Laws pp. 584–585 (emphasis added).

the miscarriage of any pregnant woman or women supposed by such person to be pregnant, unless the same be necessary to preserve her life, shall administer to her, advise, or prescribe for her, or cause to be taken by her any poison, drug, medicine, or other noxious thing, or shall use any instrument or other means whatsoever, or shall aid, assist, or counsel any person so intending to procure a miscarriage, whether said miscarriage be accomplished or not, shall be guilty of a felony, and upon conviction thereof shall be fined not less than one hundred dollars nor more than five hundred dollars and be imprisoned for a term not exceeding five years nor less than one year." 102

34. Tennessee (1883):

Sec. 1. "That every person who shall administer to any woman pregnant with child, whether such child be quick or not, any medicine, drug or substance whatever, or shall use or employ any instrument, or other means whatever with intent to destroy such child, and shall thereby destroy such child before its birth, unless the same shall have been done with a view to preserve the life of the mother, shall be punished by imprisonment in the penitentiary not less than one nor more than five years."

Sec. 2. "Every person who shall administer any substance with the intention to procure the miscarriage of a woman then being with child, or shall use or employ any instrument or other means with such intent, unless the same shall have been done with a view to preserve the life of such mother, shall be punished by imprisonment in the penitentiary not less than one nor more than three years." ¹⁰³

¹⁰² 1883 Del. Laws, ch. 226 (emphasis added).

¹⁰³ 1883 Tenn. Acts pp. 188–189 (emphasis added).

35. South Carolina (1883):

Sec. 1. "That any person who shall administer to any woman with child, or prescribe for any such woman, or suggest to or advise or procure her to take, any medicine, substance, drug or thing whatever, or who shall use or employ, or advise the use or employment of, any instrument or other means of force whatever, with intent thereby to cause or procure the miscarriage or abortion or premature labor of any such woman, unless the same shall have been necessary to preserve her life, or the life of such child, shall, in case the death of such child or of such woman results in whole or in part therefrom, be deemed guilty of a felony, and, upon conviction thereof, shall be punished by imprisonment in the Penitentiary for a term not more than twenty years nor less than five years."

Sec. 2. "That any person who shall administer to any woman with child, or prescribe or procure or provide for any such woman, or advise or procure any such woman to take, any medicine, drug, substance or thing whatever, or shall use or employ or advise the use or employment of, any instrument or other means of force whatever, with intent thereby to cause or procure the miscarriage or abortion or premature labor of any such woman, shall, upon conviction thereof, be punished by imprisonment in the Penitentiary for a term not more than five years, or by fine not more than five thousand dollars, or by such fine and imprisonment both, at the discretion of the Court; but no conviction shall be had under the provisions of Section 1 or 2 of this Act upon the uncorroborated evidence of such woman." 104

36. Kentucky (1910):

Sec. 1. "It shall be unlawful for any person to prescribe or administer to any pregnant woman, or to any

¹⁰⁴ 1883 S. C. Acts pp. 547–548 (emphasis added).

woman whom he has reason to believe pregnant, at any time during the period of gestation, any drug, medicine or substance, whatsoever, with the intent thereby to procure the miscarriage of such woman, or with like intent, to use any instrument or means whatsoever, unless such miscarriage is necessary to preserve her life; and any person so offending, shall be punished by a fine of not less than five hundred nor more than one thousand dollars, and imprisoned in the State prison for not less than one nor more than ten years."

Sec. 2. "If by reason of any of the acts described in Section 1 hereof, the miscarriage of such woman is procured, and she does miscarry, causing the death of the unborn child, whether before or after quickening time, the person so offending shall be guilty of a felony, and confined in the penitentiary for not less than two, nor more than twenty-one years."

Sec. 3. "If, by reason of the commission of any of the acts described in Section 1 hereof, the woman to whom such drug or substance has been administered, or upon whom such instrument has been used, shall die, the person offending shall be punished as now prescribed by law, for the offense of murder or manslaughter, as the facts may justify."

Sec. 4. "The consent of the woman to the performance of the operation or administering of the medicines or substances, referred to, shall be no defense, and she shall be a competent witness in any prosecution under this act, and for that purpose she shall not be considered an accomplice." ¹⁰⁵

37. Mississippi (1952):

Sec. 1. "Whoever, by means of any instrument, medicine, drug, or other means whatever shall willfully and

¹⁰⁵ 1910 Ky. Acts pp. 189–190 (emphasis added).

knowingly cause any woman pregnant with child to abort or miscarry, or attempts to procure or produce an abortion or miscarriage, unless the same were done as necessary for the preservation of the mother's life, shall be imprisoned in the state penitentiary no less than one (1) year, nor more than ten (10) years; or if the death of the mother results therefrom, the person procuring, causing, or attempting to procure or cause the abortion or miscarriage shall be guilty of murder."

Sec. 2. "No act prohibited in section 1 hereof shall be considered as necessary for the preservation of the mother's life unless upon the prior advice, in writing, of two reputable licensed physicians."

Sec. 3. "The license of any physician or nurse shall be automatically revoked upon conviction under the provisions of this act." ¹⁰⁶

B

This appendix contains statutes criminalizing abortion at all stages in each of the Territories that became States and in the District of Columbia. The statutes appear in chronological order of enactment.

1. Hawaii (1850):

Sec. 1. "Whoever maliciously, without lawful justification, administers, or causes or procures to be administered any poison or noxious thing to a woman then with child, in order to produce her mis-carriage, or maliciously uses any instrument or other means with like intent, shall, if such woman be then quick with child, be punished by fine not exceeding one thousand dollars and imprisonment at hard labor not more than five years. And if she be then not quick with child, shall be punished by a fine not exceeding five hundred dollars,

 $^{^{106}1952}$ Miss. Laws p. 289 (codified at Miss. Code Ann. §2223 (1956) (emphasis added)).

and imprisonment at hard labor not more than two vears."

Sec. 2. "Where means of causing abortion are used for the purpose of saving the life of the woman, the surgeon or other person using such means is lawfully justified." ¹⁰⁷

2. Washington (1854):

Sec. 37. "Every person who shall administer to any woman pregnant with a quick child, any medicine, drug, or substance whatever, or shall use or employ any instrument, or other means, with intent thereby to destroy such child, unless the same shall have been necessary to preserve the life of such mother, shall, in case the death of such child or of such mother be thereby produced, on conviction thereof, be imprisoned in the penitentiary not more than twenty years, nor less than one year."

Sec. 38. "Every person who shall administer to any pregnant woman, or to any woman who he supposes to be pregnant, any medicine, drug, or substance whatever, or shall use or employ any instrument, or other means, thereby to procure the miscarriage of such woman, unless the same is necessary to preserve her life, shall on conviction thereof, be imprisoned in the penitentiary not more than five years, nor less than one year, or be imprisoned in the county jail not more than twelve months, nor less than one month, and be fined in any sum not exceeding one thousand dollars." 108

3. Colorado (1861):

 $^{^{107}\}mathrm{Haw}.$ Penal Code, ch. 12, §§1–2 (1850) (emphasis added). Hawaii became a State in 1959. See Presidential Proclamation No. 3309, 73 Stat. c74–c75.

¹⁰⁸Terr. of Wash. Stat., ch. 2, §§37–38, p. 81 (1854) (emphasis added). Washington became a State in 1889. See Presidential Proclamation No. 8, 26 Stat. 1552–1553.

Sec. 42. "[E]very person who shall administer substance or liquid, or who shall use or cause to be used any instrument, of whatsoever kind, with the intention to procure the miscarriage of any woman then being with child, and shall thereof be duly convicted, shall be imprisoned for a term not exceeding three years, and fined in a sum not exceeding one thousand dollars; and if any woman, by reason of such treatment, shall die, the person or persons administering, or causing to be administered, such poison, substance or liquid, or using or causing to be used, any instrument, as aforesaid, shall be deemed guilty of manslaughter, and if convicted, be punished accordingly." 109

4. Idaho (1864):

Sec. 42. "[E]very person who shall administer or cause to be administered, or taken, any medicinal substance, or shall use or cause to be used, any instruments whatever, with the intention to procure the miscarriage of any woman then being with child, and shall be thereof duly convicted, shall be punished by imprisonment in the territorial prison for a term not less than two years, nor more than five years: Provided, That no physician shall be effected by the last clause of this section, who in the discharge of his professional duties, deems it necessary to produce the miscarriage of any woman in order to save her life." 110

5. Montana (1864):

Sec. 41. "[E]very person who shall administer, or cause to be administered, or taken, any medicinal substance, or shall use, or cause to be used, any instru-

¹⁰⁹1861 Terr. of Colo. Gen. Laws pp. 296–297. Colorado became a State in 1876. See Presidential Proclamation No. 7, 19 Stat. 665–666.

 $^{^{110}1863{-}1864}$ Terr. of Idaho Laws p. 443. Idaho became a State in 1890. See 26 Stat. 215 ${-}219$.

ments whatever, with the intention to produce the miscarriage of any woman then being with child, and shall be thereof duly convicted, shall be punished by imprisonment in the Territorial prison for a term not less than two years nor more than five years. Provided, That no physician shall be affected by the last clause of this section, who in the discharge of his professional duties deems it necessary to produce the miscarriage of any woman in order to save her life."111

6. Arizona (1865):

Sec. 45. "[E]very person who shall administer or cause to be administered or taken, any medicinal substances, or shall use or cause to be used any instruments whatever, with the intention to procure the miscarriage of any woman then being with child, and shall be thereof duly convicted, shall be punished by imprisonment in the Territorial prison for a term not less than two years nor more than five years: Provided, that no physician shall be affected by the last clause of this section, who in the discharge of his professional duties, deems it necessary to produce the miscarriage of any woman in order to save her life." 112

7. Wyoming (1869):

Sec. 25. "[A]ny person who shall administer, or cause to be administered, or taken, any such poison, substance or liquid, or who shall use, or cause to be used, any instrument of whatsoever kind, with the intention to procure the miscarriage of any woman then being with child, and shall thereof be duly convicted, shall be imprisoned for a term not exceeding three

¹¹¹1864 Terr. of Mont. Laws p. 184. Montana became a State in 1889. See Presidential Proclamation No. 7, 26 Stat. 1551–1552.

¹¹²Howell Code, ch. 10, §45 (1865). Arizona became a State in 1912. See Presidential Proclamation of Feb. 14, 1912, 37 Stat. 1728–1729.

years, in the penitentiary, and fined in a sum not exceeding one thousand dollars; and if any woman by reason of such treatment shall die, the person, or persons, administering, or causing to be administered such poison, substance, or liquid, or using or causing to be used, any instrument, as aforesaid, shall be deemed guilty of manslaughter, and if convicted, be punished by imprisonment for a term not less than three years in the penitentiary, and fined in a sum not exceeding one thousand dollars, unless it appear that such miscarriage was procured or attempted by, or under advice of a physician or surgeon, with intent to save the life of such woman, or to prevent serious and permanent bodily injury to her." 113

8. Utah (1876):

Sec. 142. "Every person who provides, supplies, or administers to any pregnant woman, or procures any such woman to take any medicine, drug, or substance, or uses or employs any instrument or other means whatever, with intent thereby to procure the miscarriage of such woman, unless the same is necessary to preserve her life, is punishable by imprisonment in the penitentiary not less than two nor more than ten years." ¹¹⁴

9. North Dakota (1877):

Sec. 337. "Every person who administers to any pregnant woman, or who prescribes for any such woman, or advises or procures any such woman to take any medicine, drug or substance, or uses or employs

¹¹³1869 Terr. of Wyo. Gen. Laws p. 104 (emphasis added). Wyoming became a State in 1889. See 26 Stat. 222–226.

¹¹⁴Terr. of Utah Comp. Laws §1972 (1876) (emphasis added). Utah became a State in 1896. See Presidential Proclamation No. 9, 29 Stat. 876–877.

any instrument, or other means whatever with intent thereby to procure the miscarriage of such woman, unless the same is necessary to preserve her life, is punishable by imprisonment in the territorial prison not exceeding three years, or in a county jail not exceeding one year."¹¹⁵

10. South Dakota (1877): Same as North Dakota.

11. Oklahoma (1890):

Sec. 2187. "Every person who administers to any pregnant woman, or who prescribes for any such woman, or advises or procures any such woman to take any medicine, drug or substance, or uses or employs any instrument, or other means whatever, with intent thereby to procure the miscarriage of such woman, unless the same is necessary to preserve her life, is punishable by imprisonment in the Territorial prison not exceeding three years, or in a county jail not exceeding one year." 116

12. Alaska (1899):

Sec. 8. "That if any person shall administer to any woman pregnant with a child any medicine, drug, or substance whatever, or shall use any instrument or other means, with intent thereby to destroy such child, unless the same shall be necessary to preserve the life of such mother, such person shall, in case the death of such child or mother be thereby produced, be deemed

 $^{^{115}\}mathrm{Dakota}$ Penal Code §337 (1877) (codified at N. D. Rev. Code §7177 (1895)), and S. D. Rev. Penal Code Ann. §337 (1883). North and South Dakota became States in 1889. See Presidential Proclamation No. 5, 26 Stat. 1548–1551.

¹¹⁶Okla. Stat. §2187 (1890) (emphasis added). Oklahoma became a State in 1907. See Presidential Proclamation of Nov. 16, 1907, 35 Stat. 2160–2161.

guilty of manslaughter, and shall be punished accordingly."117

13. New Mexico (1919):

Sec. 1. "Any person who shall administer to any pregnant woman any medicine, drug or substance whatever, or attempt by operation or any other method or means to produce an abortion or miscarriage upon such woman, shall be guilty of a felony, and, upon conviction thereof, shall be fined not more than two thousand (\$2,000.00) Dollars, nor less than five hundred (\$500.00) Dollars, or imprisoned in the penitentiary for a period of not less than one nor more than five years, or by both such fine and imprisonment in the discretion of the court trying the case."

Sec. 2. "Any person committing such act or acts mentioned in section one hereof which shall culminate in the death of the woman shall be deemed guilty of murder in the second degree; *Provided*, however, an abortion may be produced when two physicians licensed to practice in the State of New Mexico, in consultation, deem it necessary to preserve the life of the woman, or to prevent serious and permanent bodily injury."

Sec. 3. "For the purpose of the act, the term "pregnancy" is defined as that condition of a woman from the date of conception to the birth of her child."¹¹⁸

* * *

District of Columbia (1901):

Sec. 809. "Whoever, with intent to procure the miscarriage of any woman, prescribes or administers to her

 $^{^{117}1899}$ Alaska Sess. Laws ch. 2, p. 3 (emphasis added). Alaska became a State in 1959. See Presidential Proclamation No. 3269, 73 Stat. c16.

¹¹⁸N. M. Laws p. 6 (emphasis added). New Mexico became a State in 1912. See Presidential Proclamation of Jan. 6, 1912, 37 Stat. 1723–1724.

any medicine, drug, or substance whatever, or with like intent uses any instrument or means, unless when necessary to preserve her life or health and under the direction of a competent licensed practitioner of medicine, shall be imprisoned for not more than five years; or if the woman or her child dies in consequence of such act, by imprisonment for not less than three nor more than twenty years."¹¹⁹

 $^{^{119}\,\}S 809,\, 31$ Stat. 1322 (1901) (emphasis added).

SUPREME COURT OF THE UNITED STATES

No. 19-1392

THOMAS E. DOBBS, STATE HEALTH OFFICER OF THE MISSISSIPPI DEPARTMENT OF HEALTH, ET AL., PETITIONERS v. JACKSON WOMEN'S HEALTH ORGANIZATION, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

[June 24, 2022]

JUSTICE THOMAS, concurring.

I join the opinion of the Court because it correctly holds that there is no constitutional right to abortion. Respondents invoke one source for that right: the Fourteenth Amendment's guarantee that no State shall "deprive any person of life, liberty, or property without due process of law." The Court well explains why, under our substantive due process precedents, the purported right to abortion is not a form of "liberty" protected by the Due Process Clause. Such a right is neither "deeply rooted in this Nation's history and tradition" nor "implicit in the concept of ordered liberty." Washington v. Glucksberg, 521 U.S. 702, 721 (1997) (internal quotation marks omitted). "[T]he idea that the Framers of the Fourteenth Amendment understood the Due Process Clause to protect a right to abortion is farcical." June Medical Services L. L. C. v. Russo, 591 U. S. ____, ___ (2020) (THOMAS, J., dissenting) (slip op., at 17).

I write separately to emphasize a second, more fundamental reason why there is no abortion guarantee lurking in the Due Process Clause. Considerable historical evidence indicates that "due process of law" merely required executive and judicial actors to comply with legislative enactments and the common law when depriving a person of

life, liberty, or property. See, e.g., Johnson v. United States, 576 U. S. 591, 623 (2015) (THOMAS, J., concurring in judgment). Other sources, by contrast, suggest that "due process of law" prohibited legislatures "from authorizing the deprivation of a person's life, liberty, or property without providing him the customary procedures to which freemen were entitled by the old law of England." *United States* v. Vaello Madero, 596 U. S. ____, ____ (2022) (THOMAS, J., concurring) (slip op., at 3) (internal quotation marks omitted). Either way, the Due Process Clause at most guarantees process. It does not, as the Court's substantive due process cases suppose, "forbi[d] the government to infringe certain 'fundamental' liberty interests at all, no matter what process is provided." Reno v. Flores, 507 U. S. 292, 302 (1993); see also, e.g., Collins v. Harker Heights, 503 U.S. 115, 125 (1992).

As I have previously explained, "substantive due process" is an oxymoron that "lack[s] any basis in the Constitution." Johnson, 576 U.S., at 607–608 (opinion of THOMAS, J.); see also, e.g., Vaello Madero, 596 U.S., at ___ (THOMAS, J., concurring) (slip op., at 3) ("[T]ext and history provide little support for modern substantive due process doctrine"). "The notion that a constitutional provision that guarantees only 'process' before a person is deprived of life, liberty, or property could define the substance of those rights strains credulity for even the most casual user of words." McDonald v. Chicago, 561 U. S. 742, 811 (2010) (THOMAS, J., concurring in part and concurring in judgment); see also United States v. Carlton, 512 U. S. 26, 40 (1994) (Scalia, J., concurring in judgment). The resolution of this case is thus straightforward. Because the Due Process Clause does not secure any substantive rights, it does not secure a right to abortion.

The Court today declines to disturb substantive due process jurisprudence generally or the doctrine's application in other, specific contexts. Cases like *Griswold* v. *Connecticut*,

Cite as: 597 U.S. ____ (2022)

THOMAS, J., concurring

381 U. S. 479 (1965) (right of married persons to obtain contraceptives)*; Lawrence v. Texas, 539 U. S. 558 (2003) (right to engage in private, consensual sexual acts); and Obergefell v. Hodges, 576 U. S. 644 (2015) (right to same-sex marriage), are not at issue. The Court's abortion cases are unique, see ante, at 31–32, 66, 71–72, and no party has asked us to decide "whether our entire Fourteenth Amendment jurisprudence must be preserved or revised," McDonald, 561 U. S., at 813 (opinion of THOMAS, J.). Thus, I agree that "[n]othing in [the Court's] opinion should be understood to cast doubt on precedents that do not concern abortion." Ante, at 66.

For that reason, in future cases, we should reconsider all of this Court's substantive due process precedents, including Griswold, Lawrence, and Obergefell. Because any substantive due process decision is "demonstrably erroneous," Ramos v. Louisiana, 590 U. S. ____, ___ (2020) (THOMAS, J., concurring in judgment) (slip op., at 7), we have a duty to "correct the error" established in those precedents, Gamble v. United States, 587 U.S. ____, ___ (2019) (THOMAS, J., concurring) (slip op., at 9). After overruling these demonstrably erroneous decisions, the question would remain whether other constitutional provisions guarantee the myriad rights that our substantive due process cases have generated. For example, we could consider whether any of the rights announced in this Court's substantive due process cases are "privileges or immunities of citizens of the United States" protected by the Fourteenth Amendment. Amdt.

^{*}Griswold v. Connecticut purported not to rely on the Due Process Clause, but rather reasoned "that specific guarantees in the Bill of Rights"—including rights enumerated in the First, Third, Fourth, Fifth, and Ninth Amendments—"have penumbras, formed by emanations," that create "zones of privacy." 381 U. S., at 484. Since Griswold, the Court, perhaps recognizing the facial absurdity of Griswold's penumbral argument, has characterized the decision as one rooted in substantive due process. See, e.g., Obergefell v. Hodges, 576 U. S. 644, 663 (2015); Washington v. Glucksberg, 521 U. S. 702, 720 (1997).

14, §1; see *McDonald*, 561 U. S., at 806 (opinion of THOMAS, J.). To answer that question, we would need to decide important antecedent questions, including whether the Privileges or Immunities Clause protects *any* rights that are not enumerated in the Constitution and, if so, how to identify those rights. See *id.*, at 854. That said, even if the Clause does protect unenumerated rights, the Court conclusively demonstrates that abortion is not one of them under any plausible interpretive approach. See *ante*, at 15, n. 22.

Moreover, apart from being a demonstrably incorrect reading of the Due Process Clause, the "legal fiction" of substantive due process is "particularly dangerous." *McDonald*, 561 U. S., at 811 (opinion of THOMAS, J.); accord, *Obergefell*, 576 U. S., at 722 (THOMAS, J., dissenting). At least three dangers favor jettisoning the doctrine entirely.

First, "substantive due process exalts judges at the expense of the People from whom they derive their authority." *Ibid*. Because the Due Process Clause "speaks only to 'process,' the Court has long struggled to define what substantive rights it protects." Timbs v. Indiana, 586 U.S. ____, ___ (2019) (THOMAS, J., concurring in judgment) (slip op., at 2) (internal quotation marks omitted). In practice, the Court's approach for identifying those "fundamental" rights "unquestionably involves policymaking rather than neutral legal analysis." Carlton, 512 U.S., at 41–42 (opinion of Scalia, J.); see also McDonald, 561 U.S., at 812 (opinion of THOMAS, J.) (substantive due process is "a jurisprudence devoid of a guiding principle"). The Court divines new rights in line with "its own, extraconstitutional value preferences" and nullifies state laws that do not align with the judicially created guarantees. Thornburgh v. American College of Obstetricians and Gynecologists, 476 U.S. 747, 794 (1986) (White, J., dissenting).

Nowhere is this exaltation of judicial policymaking clearer than this Court's abortion jurisprudence. In *Roe* v. *Wade*, 410 U. S. 113 (1973), the Court divined a right to

abortion because it "fe[lt]" that "the Fourteenth Amendment's concept of personal liberty" included a "right of privacy" that "is broad enough to encompass a woman's decision whether or not to terminate her pregnancy." Id., at 153. In Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833 (1992), the Court likewise identified an abortion guarantee in "the liberty protected by the Fourteenth Amendment," but, rather than a "right of privacy," it invoked an ethereal "right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life." Id., at 851. As the Court's preferred manifestation of "liberty" changed, so, too, did the test used to protect it, as Roe's author lamented. See Casey, 505 U.S., at 930 (Blackmun, J., concurring in part and dissenting in part) ("[T]he Roe framework is far more administrable, and far less manipulable, than the 'undue burden' standard").

Now, in this case, the nature of the purported "liberty" supporting the abortion right has shifted yet again. Respondents and the United States propose no fewer than three different interests that supposedly spring from the Due Process Clause. They include "bodily integrity," "personal autonomy in matters of family, medical care, and faith," Brief for Respondents 21, and "women's equal citizenship," Brief for United States as *Amicus Curiae* 24. That 50 years have passed since *Roe* and abortion advocates still cannot coherently articulate the right (or rights) at stake proves the obvious: The right to abortion is ultimately a policy goal in desperate search of a constitutional justification.

Second, substantive due process distorts other areas of constitutional law. For example, once this Court identifies a "fundamental" right for one class of individuals, it invokes the Equal Protection Clause to demand exacting scrutiny of statutes that deny the right to others. See, *e.g.*, *Eisenstadt* v. *Baird*, 405 U. S. 438, 453–454 (1972) (relying on *Griswold* to invalidate a state statute prohibiting distribution

of contraceptives to unmarried persons). Statutory classifications implicating certain "nonfundamental" rights, meanwhile, receive only cursory review. See, e.g., Armour v. Indianapolis, 566 U.S. 673, 680 (2012). Similarly, this Court deems unconstitutionally "vague" or "overbroad" those laws that impinge on its preferred rights, while letting slide those laws that implicate supposedly lesser values. See, e.g., Johnson, 576 U.S., at 618–621 (opinion of THOMAS, J.); United States v. Sineneng-Smith, 590 U.S. ___, ____ (2020) (THOMAS, J., concurring) (slip op., at 3–5). "In fact, our vagueness doctrine served as the basis for the first draft of the majority opinion in Roe v. Wade," and it since has been "deployed . . . to nullify even mild regulations of the abortion industry." Johnson, 576 U.S., at 620–621 (opinion of THOMAS, J.). Therefore, regardless of the doctrinal context, the Court often "demand[s] extra justifications for encroachments" on "preferred rights" while "relax[ing] purstandards of review portedly higher preferred rights." Whole Woman's Health v. Hellerstedt, 579 U.S. 582, 640–642 (2016) (THOMAS, J., dissenting). Substantive due process is the core inspiration for many of the Court's constitutionally unmoored policy judgments.

Third, substantive due process is often wielded to "disastrous ends." *Gamble*, 587 U. S., at ____ (THOMAS, J., concurring) (slip op., at 16). For instance, in *Dred Scott* v. *Sandford*, 19 How. 393 (1857), the Court invoked a species of substantive due process to announce that Congress was powerless to emancipate slaves brought into the federal territories. See *id.*, at 452. While *Dred Scott* "was overruled on the battlefields of the Civil War and by constitutional amendment after Appomattox," *Obergefell*, 576 U. S., at 696 (ROBERTS, C. J., dissenting), that overruling was "[p]urchased at the price of immeasurable human suffering," *Adarand Constructors, Inc.* v. *Peña*, 515 U. S. 200, 240 (1995) (THOMAS, J., concurring in part and concurring in judgment). Now today, the Court rightly overrules *Roe* and

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Casey—two of this Court's "most notoriously incorrect" substantive due process decisions, *Timbs*, 586 U. S., at ____ (opinion of Thomas, J.) (slip op., at 2)—after more than 63 million abortions have been performed, see National Right to Life Committee, Abortion Statistics (Jan. 2022), https://www.nrlc.org/uploads/factsheets/FS01AbortionintheUS.pdf. The harm caused by this Court's forays into substantive due process remains immeasurable.

* * *

Because the Court properly applies our substantive due process precedents to reject the fabrication of a constitutional right to abortion, and because this case does not present the opportunity to reject substantive due process entirely, I join the Court's opinion. But, in future cases, we should "follow the text of the Constitution, which sets forth certain substantive rights that cannot be taken away, and adds, beyond that, a right to due process when life, liberty, or property is to be taken away." *Carlton*, 512 U. S., at 42 (opinion of Scalia, J.). Substantive due process conflicts with that textual command and has harmed our country in many ways. Accordingly, we should eliminate it from our jurisprudence at the earliest opportunity.

SUPREME COURT OF THE UNITED STATES

No. 19-1392

THOMAS E. DOBBS, STATE HEALTH OFFICER OF THE MISSISSIPPI DEPARTMENT OF HEALTH, ET AL., PETITIONERS v. JACKSON WOMEN'S HEALTH ORGANIZATION, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

[June 24, 2022]

JUSTICE KAVANAUGH, concurring.

I write separately to explain my additional views about why *Roe* was wrongly decided, why *Roe* should be overruled at this time, and the future implications of today's decision.

T

Abortion is a profoundly difficult and contentious issue because it presents an irreconcilable conflict between the interests of a pregnant woman who seeks an abortion and the interests in protecting fetal life. The interests on both sides of the abortion issue are extraordinarily weighty.

On the one side, many pro-choice advocates forcefully argue that the ability to obtain an abortion is critically important for women's personal and professional lives, and for women's health. They contend that the widespread availability of abortion has been essential for women to advance in society and to achieve greater equality over the last 50 years. And they maintain that women must have the freedom to choose for themselves whether to have an abortion.

On the other side, many pro-life advocates forcefully argue that a fetus is a human life. They contend that all human life should be protected as a matter of human dignity

and fundamental morality. And they stress that a significant percentage of Americans with pro-life views are women.

When it comes to abortion, one interest must prevail over the other at any given point in a pregnancy. Many Americans of good faith would prioritize the interests of the pregnant woman. Many other Americans of good faith instead would prioritize the interests in protecting fetal life—at least unless, for example, an abortion is necessary to save the life of the mother. Of course, many Americans are conflicted or have nuanced views that may vary depending on the particular time in pregnancy, or the particular circumstances of a pregnancy.

The issue before this Court, however, is not the policy or morality of abortion. The issue before this Court is what the Constitution says about abortion. The Constitution does not take sides on the issue of abortion. The text of the Constitution does not refer to or encompass abortion. To be sure, this Court has held that the Constitution protects unenumerated rights that are deeply rooted in this Nation's history and tradition, and implicit in the concept of ordered liberty. But a right to abortion is not deeply rooted in American history and tradition, as the Court today thoroughly explains.¹

On the question of abortion, the Constitution is therefore neither pro-life nor pro-choice. The Constitution is neutral and leaves the issue for the people and their elected representatives to resolve through the democratic process in the

¹The Court's opinion today also recounts the pre-constitutional common-law history in England. That English history supplies background information on the issue of abortion. As I see it, the dispositive point in analyzing American history and tradition for purposes of the Fourteenth Amendment inquiry is that abortion was largely prohibited in most American States as of 1868 when the Fourteenth Amendment was ratified, and that abortion remained largely prohibited in most American States until *Roe* was decided in 1973.

States or Congress—like the numerous other difficult questions of American social and economic policy that the Constitution does not address.

Because the Constitution is neutral on the issue of abortion, this Court also must be scrupulously neutral. The nine unelected Members of this Court do not possess the constitutional authority to override the democratic process and to decree either a pro-life or a pro-choice abortion policy for all 330 million people in the United States.

Instead of adhering to the Constitution's neutrality, the Court in *Roe* took sides on the issue and unilaterally decreed that abortion was legal throughout the United States up to the point of viability (about 24 weeks of pregnancy). The Court's decision today properly returns the Court to a position of neutrality and restores the people's authority to address the issue of abortion through the processes of democratic self-government established by the Constitution.

Some *amicus* briefs argue that the Court today should not only overrule *Roe* and return to a position of judicial neutrality on abortion, but should go further and hold that the Constitution *outlaws* abortion throughout the United States. No Justice of this Court has ever advanced that position. I respect those who advocate for that position, just as I respect those who argue that this Court should hold that the Constitution legalizes pre-viability abortion throughout the United States. But both positions are wrong as a constitutional matter, in my view. The Constitution neither outlaws abortion nor legalizes abortion.

To be clear, then, the Court's decision today does not outlaw abortion throughout the United States. On the contrary, the Court's decision properly leaves the question of abortion for the people and their elected representatives in the democratic process. Through that democratic process, the people and their representatives may decide to allow or limit abortion. As Justice Scalia stated, the "States may, if they wish, permit abortion on demand, but the Constitution does not require them to do so." Planned Parenthood of Southeastern Pa. v. Casey, 505 U. S. 833, 979 (1992) (opinion concurring in judgment in part and dissenting in part).

Today's decision therefore does not prevent the numerous States that readily allow abortion from continuing to readily allow abortion. That includes, if they choose, the *amici* States supporting the plaintiff in this Court: New York, California, Illinois, Maine, Massachusetts, Rhode Island, Vermont, Connecticut, New Jersey, Pennsylvania, Delaware, Maryland, Michigan, Wisconsin, Minnesota, New Mexico, Colorado, Nevada, Oregon, Washington, and Hawaii. By contrast, other States may maintain laws that more strictly limit abortion. After today's decision, all of the States may evaluate the competing interests and decide how to address this consequential issue.²

In arguing for a constitutional right to abortion that would override the people's choices in the democratic process, the plaintiff Jackson Women's Health Organization and its amici emphasize that the Constitution does not freeze the American people's rights as of 1791 or 1868. I fully agree. To begin, I agree that constitutional rights apply to situations that were unforeseen in 1791 or 1868—such as applying the First Amendment to the Internet or the Fourth Amendment to cars. Moreover, the Constitution authorizes the creation of new rights—state and federal, statutory and constitutional. But when it comes to creating new rights, the Constitution directs the people to the various processes of democratic self-government contemplated by the Constitution—state legislation, state constitutional amendments, federal legislation, and federal constitutional

²In his dissent in *Roe*, Justice Rehnquist indicated that an exception to a State's restriction on abortion would be constitutionally required when an abortion is necessary to save the life of the mother. See *Roe* v. *Wade*, 410 U. S. 113, 173 (1973). Abortion statutes traditionally and currently provide for an exception when an abortion is necessary to protect the life of the mother. Some statutes also provide other exceptions.

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amendments. See generally Amdt. 9; Amdt. 10; Art. I, §8; Art. V; J. Sutton, 51 Imperfect Solutions: States and the Making of American Constitutional Law 7–21, 203–216 (2018); A. Amar, America's Constitution: A Biography 285–291, 315–347 (2005).

The Constitution does not grant the nine unelected Members of this Court the unilateral authority to rewrite the Constitution to create new rights and liberties based on our own moral or policy views. As Justice Rehnquist stated, this Court has not "been granted a roving commission, either by the Founding Fathers or by the framers of the Fourteenth Amendment, to strike down laws that are based upon notions of policy or morality suddenly found unacceptable by a majority of this Court." Furman v. Georgia, 408 U. S. 238, 467 (1972) (dissenting opinion); see Washington v. Glucksberg, 521 U. S. 702, 720–721 (1997); Cruzan v. Director, Mo. Dept. of Health, 497 U. S. 261, 292–293 (1990) (Scalia, J., concurring).

This Court therefore does not possess the authority either to declare a constitutional right to abortion or to declare a constitutional prohibition of abortion. See Casey, 505 U. S., at 953 (Rehnquist, C. J., concurring in judgment in part and dissenting in part); id., at 980 (opinion of Scalia, J.); Roe v. Wade, 410 U. S. 113, 177 (1973) (Rehnquist, J., dissenting); Doe v. Bolton, 410 U. S. 179, 222 (1973) (White, J., dissenting).

In sum, the Constitution is neutral on the issue of abortion and allows the people and their elected representatives to address the issue through the democratic process. In my respectful view, the Court in *Roe* therefore erred by taking sides on the issue of abortion.

II

The more difficult question in this case is *stare decisis*—that is, whether to overrule the *Roe* decision.

The principle of stare decisis requires respect for the

Court's precedents and for the accumulated wisdom of the judges who have previously addressed the same issue. *Stare decisis* is rooted in Article III of the Constitution and is fundamental to the American judicial system and to the stability of American law.

Adherence to precedent is the norm, and *stare decisis* imposes a high bar before this Court may overrule a precedent. This Court's history shows, however, that *stare decisis* is not absolute, and indeed cannot be absolute. Otherwise, as the Court today explains, many long-since-overruled cases such as *Plessy* v. *Ferguson*, 163 U. S. 537 (1896); *Lochner* v. *New York*, 198 U. S. 45 (1905); *Minersville School Dist.* v. *Gobitis*, 310 U. S. 586 (1940); and *Bowers* v. *Hardwick*, 478 U. S. 186 (1986), would never have been overruled and would still be the law.

In his canonical *Burnet* opinion in 1932, Justice Brandeis stated that in "cases involving the Federal Constitution, where correction through legislative action is practically impossible, this Court has often overruled its earlier decisions." Burnet v. Coronado Oil & Gas Co., 285 U.S. 393, 406-407 (1932) (dissenting opinion). That description of the Court's practice remains accurate today. Every current Member of this Court has voted to overrule precedent. And over the last 100 years beginning with Chief Justice Taft's appointment in 1921, every one of the 48 Justices appointed to this Court has voted to overrule precedent. Many of those Justices have voted to overrule a substantial number of very significant and longstanding precedents. See, e.g., Obergefell v. Hodges, 576 U. S. 644 (2015) (overruling Baker v. Nelson); Brown v. Board of Education, 347 U.S. 483 (1954) (overruling Plessy v. Ferguson); West Coast Hotel Co. v. Parrish, 300 U. S. 379 (1937) (overruling Adkins v. Children's Hospital of D. C. and in effect Lochner v. New York).

But that history alone does not answer the critical question: When precisely should the Court overrule an erroneous constitutional precedent? The history of *stare decisis* in

Applying those factors, I agree with the Court today that *Roe* should be overruled. The Court in *Roe* erroneously assigned itself the authority to decide a critically important moral and policy issue that the Constitution does not grant this Court the authority to decide. As Justice Byron White succinctly explained, *Roe* was "an improvident and extravagant exercise of the power of judicial review" because "nothing in the language or history of the Constitution" supports a constitutional right to abortion. *Bolton*, 410 U. S., at 221–222 (dissenting opinion).

Of course, the fact that a precedent is wrong, even egregiously wrong, does not alone mean that the precedent should be overruled. But as the Court today explains, *Roe* has caused significant negative jurisprudential and real-world consequences. By taking sides on a difficult and contentious issue on which the Constitution is neutral, *Roe* overreached and exceeded this Court's constitutional authority; gravely distorted the Nation's understanding of this Court's proper constitutional role; and caused significant harm to what *Roe* itself recognized as the State's "important and legitimate interest" in protecting fetal life. 410 U. S., at 162. All of that explains why tens of millions of Americans—and the 26 States that explicitly ask the Court to overrule *Roe*—do not accept *Roe* even 49 years later. Under the Court's longstanding *stare decisis* principles, *Roe*

should be overruled.3

But the *stare decisis* analysis here is somewhat more complicated because of *Casey*. In 1992, 19 years after *Roe*, *Casey* acknowledged the continuing dispute over *Roe*. The Court sought to find common ground that would resolve the abortion debate and end the national controversy. After careful and thoughtful consideration, the *Casey* plurality reaffirmed a right to abortion through viability (about 24 weeks), while also allowing somewhat more regulation of abortion than *Roe* had allowed.⁴

I have deep and unyielding respect for the Justices who wrote the *Casey* plurality opinion. And I respect the *Casey* plurality's good-faith effort to locate some middle ground or compromise that could resolve this controversy for America.

But as has become increasingly evident over time, Casey's

³I also agree with the Court's conclusion today with respect to reliance. Broad notions of societal reliance have been invoked in support of Roe, but the Court has not analyzed reliance in that way in the past. For example, American businesses and workers relied on Lochner v. New York, 198 U. S. 45 (1905), and Adkins v. Children's Hospital of D. C., 261 U.S. 525 (1923), to construct a laissez-faire economy that was free of substantial regulation. In West Coast Hotel Co. v. Parrish, 300 U. S. 379 (1937), the Court nonetheless overruled Adkins and in effect Lochner. An entire region of the country relied on *Plessy* v. *Ferguson*, 163 U.S. 537 (1896), to enforce a system of racial segregation. In Brown v. Board of Education, 347 U. S. 483 (1954), the Court overruled Plessy. Much of American society was built around the traditional view of marriage that was upheld in Baker v. Nelson, 409 U.S. 810 (1972), and that was reflected in laws ranging from tax laws to estate laws to family laws. In Obergefell v. Hodges, 576 U.S. 644 (2015), the Court nonetheless overruled Baker.

⁴As the Court today notes, *Casey*'s approach to *stare decisis* pointed in two directions. *Casey* reaffirmed *Roe*'s viability line, but it expressly overruled the *Roe* trimester framework and also expressly overruled two landmark post-*Roe* abortion cases—*Akron* v. *Akron Center for Reproductive Health, Inc.*, 462 U. S. 416 (1983), and *Thornburgh* v. *American College of Obstetricians and Gynecologists*, 476 U. S. 747 (1986). See *Casey*, 505 U. S., at 870, 872–873, 878–879, 882. *Casey* itself thus directly contradicts any notion of absolute *stare decisis* in abortion cases.

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well-intentioned effort did not resolve the abortion debate. The national division has not ended. In recent years, a significant number of States have enacted abortion restrictions that directly conflict with *Roe*. Those laws cannot be dismissed as political stunts or as outlier laws. Those numerous state laws collectively represent the sincere and deeply held views of tens of millions of Americans who continue to fervently believe that allowing abortions up to 24 weeks is far too radical and far too extreme, and does not sufficiently account for what *Roe* itself recognized as the State's "important and legitimate interest" in protecting fetal life. 410 U. S., at 162. In this case, moreover, a majority of the States—26 in all—ask the Court to overrule *Roe* and return the abortion issue to the States.

In short, *Casey*'s *stare decisis* analysis rested in part on a predictive judgment about the future development of state laws and of the people's views on the abortion issue. But that predictive judgment has not borne out. As the Court today explains, the experience over the last 30 years conflicts with *Casey*'s predictive judgment and therefore undermines *Casey*'s precedential force.⁵

In any event, although *Casey* is relevant to the *stare decisis* analysis, the question of whether to overrule *Roe* cannot be dictated by *Casey* alone. To illustrate that *stare decisis* point, consider an example. Suppose that in 1924 this Court had expressly reaffirmed *Plessy* v. *Ferguson* and upheld the States' authority to segregate people on the basis of race. Would the Court in *Brown* some 30 years later in

⁵To be clear, public opposition to a prior decision is not a basis for overruling (or reaffirming) that decision. Rather, the question of whether to overrule a precedent must be analyzed under this Court's traditional stare decisis factors. The only point here is that Casey adopted a special stare decisis principle with respect to Roe based on the idea of resolving the national controversy and ending the national division over abortion. The continued and significant opposition to Roe, as reflected in the laws and positions of numerous States, is relevant to assessing Casey on its own terms.

1954 have reaffirmed *Plessy* and upheld racially segregated schools simply because of that intervening 1924 precedent? Surely the answer is no.

In sum, I agree with the Court's application today of the principles of *stare decisis* and its conclusion that *Roe* should be overruled.

Ш

After today's decision, the nine Members of this Court will no longer decide the basic legality of pre-viability abortion for all 330 million Americans. That issue will be resolved by the people and their representatives in the democratic process in the States or Congress. But the parties' arguments have raised other related questions, and I address some of them here.

First is the question of how this decision will affect other precedents involving issues such as contraception and marriage—in particular, the decisions in *Griswold* v. Connecticut, 381 U. S. 479 (1965); Eisenstadt v. Baird, 405 U. S. 438 (1972); Loving v. Virginia, 388 U. S. 1 (1967); and Obergefell v. Hodges, 576 U. S. 644 (2015). I emphasize what the Court today states: Overruling Roe does not mean the overruling of those precedents, and does not threaten or cast doubt on those precedents.

Second, as I see it, some of the other abortion-related legal questions raised by today's decision are not especially difficult as a constitutional matter. For example, may a State bar a resident of that State from traveling to another State to obtain an abortion? In my view, the answer is no based on the constitutional right to interstate travel. May a State retroactively impose liability or punishment for an abortion that occurred before today's decision takes effect? In my view, the answer is no based on the Due Process Clause or the *Ex Post Facto* Clause. Cf. *Bouie* v. *City of Columbia*, 378 U. S. 347 (1964).

Other abortion-related legal questions may emerge in the

future. But this Court will no longer decide the fundamental question of whether abortion must be allowed throughout the United States through 6 weeks, or 12 weeks, or 15 weeks, or 24 weeks, or some other line. The Court will no longer decide how to evaluate the interests of the pregnant woman and the interests in protecting fetal life throughout pregnancy. Instead, those difficult moral and policy questions will be decided, as the Constitution dictates, by the people and their elected representatives through the constitutional processes of democratic self-government.

* * *

The *Roe* Court took sides on a consequential moral and policy issue that this Court had no constitutional authority to decide. By taking sides, the *Roe* Court distorted the Nation's understanding of this Court's proper role in the American constitutional system and thereby damaged the Court as an institution. As Justice Scalia explained, *Roe* "destroyed the compromises of the past, rendered compromise impossible for the future, and required the entire issue to be resolved uniformly, at the national level." *Casey*, 505 U. S., at 995 (opinion concurring in judgment in part and dissenting in part).

The Court's decision today properly returns the Court to a position of judicial neutrality on the issue of abortion, and properly restores the people's authority to resolve the issue of abortion through the processes of democratic selfgovernment established by the Constitution.

To be sure, many Americans will disagree with the Court's decision today. That would be true no matter how the Court decided this case. Both sides on the abortion issue believe sincerely and passionately in the rightness of their cause. Especially in those difficult and fraught circumstances, the Court must scrupulously adhere to the Constitution's neutral position on the issue of abortion.

Since 1973, more than 20 Justices of this Court have now

grappled with the divisive issue of abortion. I greatly respect all of the Justices, past and present, who have done so. Amidst extraordinary controversy and challenges, all of them have addressed the abortion issue in good faith after careful deliberation, and based on their sincere understandings of the Constitution and of precedent. I have endeavored to do the same.

In my judgment, on the issue of abortion, the Constitution is neither pro-life nor pro-choice. The Constitution is neutral, and this Court likewise must be scrupulously neutral. The Court today properly heeds the constitutional principle of judicial neutrality and returns the issue of abortion to the people and their elected representatives in the democratic process.

SUPREME COURT OF THE UNITED STATES

No. 19-1392

THOMAS E. DOBBS, STATE HEALTH OFFICER OF THE MISSISSIPPI DEPARTMENT OF HEALTH, ET AL., PETITIONERS v. JACKSON WOMEN'S HEALTH ORGANIZATION, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

[June 24, 2022]

CHIEF JUSTICE ROBERTS, concurring in the judgment.

We granted certiorari to decide one question: "Whether all pre-viability prohibitions on elective abortions are unconstitutional." Pet. for Cert. i. That question is directly implicated here: Mississippi's Gestational Age Act, Miss. Code Ann. §41–41–191 (2018), generally prohibits abortion after the fifteenth week of pregnancy—several weeks before a fetus is regarded as "viable" outside the womb. In urging our review, Mississippi stated that its case was "an ideal vehicle" to "reconsider the bright-line viability rule," and that a judgment in its favor would "not require the Court to overturn" Roe v. Wade, 410 U. S. 113 (1973), and Planned Parenthood of Southeastern Pa. v. Casey, 505 U. S. 833 (1992). Pet. for Cert. 5.

Today, the Court nonetheless rules for Mississippi by doing just that. I would take a more measured course. I agree with the Court that the viability line established by *Roe* and *Casey* should be discarded under a straightforward *stare decisis* analysis. That line never made any sense. Our abortion precedents describe the right at issue as a woman's right to choose to terminate her pregnancy. That right should therefore extend far enough to ensure a reasonable opportunity to choose, but need not extend any further—

ROBERTS, C. J., concurring in judgment

certainly not all the way to viability. Mississippi's law allows a woman three months to obtain an abortion, well beyond the point at which it is considered "late" to discover a pregnancy. See A. Ayoola, Late Recognition of Unintended Pregnancies, 32 Pub. Health Nursing 462 (2015) (pregnancy is discoverable and ordinarily discovered by six weeks of gestation). I see no sound basis for questioning the adequacy of that opportunity.

But that is all I would say, out of adherence to a simple yet fundamental principle of judicial restraint: If it is not necessary to decide more to dispose of a case, then it is necessary not to decide more. Perhaps we are not always perfect in following that command, and certainly there are cases that warrant an exception. But this is not one of them. Surely we should adhere closely to principles of judicial restraint here, where the broader path the Court chooses entails repudiating a constitutional right we have not only previously recognized, but also expressly reaffirmed applying the doctrine of stare decisis. The Court's opinion is thoughtful and thorough, but those virtues cannot compensate for the fact that its dramatic and consequential ruling is unnecessary to decide the case before us.

I

Let me begin with my agreement with the Court, on the only question we need decide here: whether to retain the rule from *Roe* and *Casey* that a woman's right to terminate her pregnancy extends up to the point that the fetus is regarded as "viable" outside the womb. I agree that this rule should be discarded.

First, this Court seriously erred in *Roe* in adopting viability as the earliest point at which a State may legislate to advance its substantial interests in the area of abortion. See *ante*, at 50–53. *Roe* set forth a rigid three-part framework anchored to viability, which more closely resembled a regulatory code than a body of constitutional law. That

framework, moreover, came out of thin air. Neither the Texas statute challenged in *Roe* nor the Georgia statute at issue in its companion case, *Doe* v. *Bolton*, 410 U. S. 179 (1973), included *any* gestational age limit. No party or *amicus* asked the Court to adopt a bright line viability rule. And as for *Casey*, arguments for or against the viability rule played only a *de minimis* role in the parties' briefing and in the oral argument. See Tr. of Oral Arg. 17–18, 51 (fleeting discussion of the viability rule).

It is thus hardly surprising that neither *Roe* nor *Casey* made a persuasive or even colorable argument for why the time for terminating a pregnancy must extend to viability. The Court's jurisprudence on this issue is a textbook illustration of the perils of deciding a question neither presented nor briefed. As has been often noted, *Roe*'s defense of the line boiled down to the circular assertion that the State's interest is compelling only when an unborn child can live outside the womb, because that is when the unborn child can live outside the womb. See 410 U. S., at 163–164; see also J. Ely, The Wages of Crying Wolf: A Comment on *Roe* v. *Wade*, 82 Yale L. J. 920, 924 (1973) (*Roe*'s reasoning "mistake[s] a definition for a syllogism").

Twenty years later, the best defense of the viability line the *Casey* plurality could conjure up was workability. See 505 U. S., at 870. But see *ante*, at 53 (opinion of the Court) (discussing the difficulties in applying the viability standard). Although the plurality attempted to add more content by opining that "it might be said that a woman who fails to act before viability has consented to the State's intervention on behalf of the developing child," *Casey*, 505 U. S., at 870, that mere suggestion provides no basis for choosing viability as the critical tipping point. A similar implied consent argument could be made with respect to a law banning abortions after fifteen weeks, well beyond the point at which nearly all women are aware that they are pregnant, A. Ayoola, M. Nettleman, M. Stommel, & R. Canady, Time

of Pregnancy Recognition and Prenatal Care Use: A Population-based Study in the United States 39 (2010) (Pregnancy Recognition). The dissent, which would retain the viability line, offers no justification for it either.

This Court's jurisprudence since Casey, moreover, has "eroded" the "underpinnings" of the viability line, such as they were. United States v. Gaudin, 515 U.S. 506, 521 (1995). The viability line is a relic of a time when we recognized only two state interests warranting regulation of abortion: maternal health and protection of "potential life." Roe, 410 U. S., at 162–163. That changed with Gonzales v. Carhart, 550 U.S. 124 (2007). There, we recognized a broader array of interests, such as drawing "a bright line that clearly distinguishes abortion and infanticide," maintaining societal ethics, and preserving the integrity of the medical profession. Id., at 157–160. The viability line has nothing to do with advancing such permissible goals. Cf. id., at 171 (Ginsburg, J., dissenting) (Gonzales "blur[red] the line, firmly drawn in Casey, between previability and postviability abortions"); see also R. Beck, Gonzales, Casey, and the Viability Rule, 103 Nw. U. L. Rev. 249, 276-279 (2009).

Consider, for example, statutes passed in a number of jurisdictions that forbid abortions after twenty weeks of pregnancy, premised on the theory that a fetus can feel pain at that stage of development. See, e.g., Ala. Code §26–23B–2 (2018). Assuming that prevention of fetal pain is a legitimate state interest after *Gonzales*, there seems to be no reason why viability would be relevant to the permissibility of such laws. The same is true of laws designed to "protect[] the integrity and ethics of the medical profession" and restrict procedures likely to "coarsen society" to the "dignity of human life." *Gonzales*, 550 U. S., at 157. Mississippi's law, for instance, was premised in part on the legislature's finding that the "dilation and evacuation" procedure is a "barbaric practice, dangerous for the maternal patient, and

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demeaning to the medical profession." Miss. Code Ann. §41–41–191(2)(b)(i)(8). That procedure accounts for most abortions performed after the first trimester—two weeks before the period at issue in this case—and "involve[s] the use of surgical instruments to crush and tear the unborn child apart." *Ibid.*; see also *Gonzales*, 550 U. S., at 135. Again, it would make little sense to focus on viability when evaluating a law based on these permissible goals.

In short, the viability rule was created outside the ordinary course of litigation, is and always has been completely unreasoned, and fails to take account of state interests since recognized as legitimate. It is indeed "telling that other countries almost uniformly eschew" a viability line. *Ante*, at 53 (opinion of the Court). Only a handful of countries, among them China and North Korea, permit elective abortions after twenty weeks; the rest have coalesced around a 12–week line. See The World's Abortion Laws, Center for Reproductive Rights (Feb. 23, 2021) (online source archived at www.supremecourt.gov) (Canada, China, Iceland, Guinea-Bissau, the Netherlands, North Korea, Singapore, and Vietnam permit elective abortions after twenty weeks). The Court rightly rejects the arbitrary viability rule today.

II

None of this, however, requires that we also take the dramatic step of altogether eliminating the abortion right first recognized in *Roe*. Mississippi itself previously argued as much to this Court in this litigation.

When the State petitioned for our review, its basic request was straightforward: "clarify whether abortion prohibitions before viability are always unconstitutional." Pet. for Cert. 14. The State made a number of strong arguments that the answer is no, *id.*, at 15–26—arguments that, as discussed, I find persuasive. And it went out of its way to make clear that it was *not* asking the Court to repudiate

entirely the right to choose whether to terminate a pregnancy: "To be clear, the questions presented in this petition do not require the Court to overturn *Roe* or *Casey*." *Id.*, at 5. Mississippi tempered that statement with an oblique one-sentence footnote intimating that, if the Court could not reconcile *Roe* and *Casey* with current facts or other cases, it "should not retain erroneous precedent." Pet. for Cert. 5–6, n. 1. But the State never argued that we should grant review for that purpose.

After we granted certiorari, however, Mississippi changed course. In its principal brief, the State bluntly announced that the Court should overrule *Roe* and *Casey*. The Constitution does not protect a right to an abortion, it argued, and a State should be able to prohibit elective abortions if a rational basis supports doing so. See Brief for Petitioners 12–13.

The Court now rewards that gambit, noting three times that the parties presented "no half-measures" and argued that "we must either reaffirm or overrule *Roe* and *Casey*." *Ante*, at 5, 8, 72. Given those two options, the majority picks the latter.

This framing is not accurate. In its brief on the merits, Mississippi in fact argued at length that a decision simply rejecting the viability rule would result in a judgment in its favor. See Brief for Petitioners 5, 38–48. But even if the State had not argued as much, it would not matter. There is no rule that parties can confine this Court to disposing of their case on a particular ground—let alone when review was sought and granted on a different one. Our established practice is instead not to "formulate a rule of constitutional law broader than is required by the precise facts to which it is to be applied." Washington State Grange v. Washington State Republican Party, 552 U. S. 442, 450 (2008) (quoting Ashwander v. TVA, 297 U. S. 288, 347 (1936) (Brandeis, J., concurring)); see also United States v. Raines, 362 U. S. 17, 21 (1960).

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Following that "fundamental principle of judicial restraint," Washington State Grange, 552 U.S., at 450, we should begin with the narrowest basis for disposition, proceeding to consider a broader one only if necessary to resolve the case at hand. See, e.g., Office of Personnel Management v. Richmond, 496 U.S. 414, 423 (1990). It is only where there is no valid narrower ground of decision that we should go on to address a broader issue, such as whether a constitutional decision should be overturned. See Federal Election Comm'n v. Wisconsin Right to Life, Inc., 551 U.S. 449, 482 (2007) (declining to address the claim that a constitutional decision should be overruled when the appellant prevailed on its narrower constitutional argument).

Here, there is a clear path to deciding this case correctly without overruling *Roe* all the way down to the studs: recognize that the viability line must be discarded, as the majority rightly does, and leave for another day whether to reject any right to an abortion at all. See *Webster* v. *Reproductive Health Services*, 492 U.S. 490, 518, 521 (1989) (plurality opinion) (rejecting *Roe*'s viability line as "rigid" and "indeterminate," while also finding "no occasion to revisit the holding of *Roe*" that, under the Constitution, a State must provide an opportunity to choose to terminate a pregnancy).

Of course, such an approach would not be available if the rationale of *Roe* and *Casey* was inextricably entangled with and dependent upon the viability standard. It is not. Our precedents in this area ground the abortion right in a woman's "right to choose." See *Carey* v. *Population Services Int'l*, 431 U. S. 678, 688–689 (1977) ("underlying foundation of the holdings" in *Roe* and *Griswold* v. *Connecticut*, 381 U. S. 479 (1965), was the "right of decision in matters of childbearing"); *Maher* v. *Roe*, 432 U. S. 464, 473 (1977) (*Roe* and other cases "recognize a constitutionally protected interest in making certain kinds of important decisions free from governmental compulsion" (internal quotation marks

omitted)); id., at 473–474 (Roe "did not declare an unqualified constitutional right to an abortion," but instead protected "the woman from unduly burdensome interference with her freedom to decide whether to terminate her pregnancy" (internal quotation marks omitted)); Webster, 492 U. S., at 520 (plurality opinion) (Roe protects "the claims of a woman to decide for herself whether or not to abort a fetus she [is] carrying"); Gonzales, 550 U.S., at 146 (a State may not "prohibit any woman from making the ultimate decision to terminate her pregnancy"). If that is the basis for *Roe*, Roe's viability line should be scrutinized from the same perspective. And there is nothing inherent in the right to choose that requires it to extend to viability or any other point, so long as a real choice is provided. See Webster, 492 U. S., at 519 (plurality opinion) (finding no reason "why the State's interest in protecting potential human life should come into existence only at the point of viability").

To be sure, in reaffirming the right to an abortion, *Casey* termed the viability rule *Roe*'s "central holding." 505 U. S., at 860. Other cases of ours have repeated that language. See, *e.g.*, *Gonzales*, 550 U. S., at 145–146. But simply declaring it does not make it so. The question in *Roe* was whether there was any right to abortion in the Constitution. See Brief for Appellants and Brief for Appellees, in *Roe* v. *Wade*, O. T. 1971, No. 70–18. How far the right extended was a concern that was separate and subsidiary, and—not surprisingly—entirely unbriefed.

The Court in *Roe* just chose to address both issues in one opinion: It first recognized a right to "choose to terminate [a] pregnancy" under the Constitution, see 410 U. S., at 129–159, and then, having done so, explained that a line should be drawn at viability such that a State could not proscribe abortion before that period, see *id.*, at 163. The viability line is a separate rule fleshing out the metes and bounds of *Roe*'s core holding. Applying principles of *stare decisis*, I would excise that additional rule—and only that

rule—from our jurisprudence.

The majority lists a number of cases that have stressed the importance of the viability rule to our abortion precedents. See *ante*, at 73–74. I agree that—whether it was originally holding or dictum—the viability line is clearly part of our "past precedent," and the Court has applied it as such in several cases since *Roe*. *Ante*, at 73. My point is that *Roe* adopted two distinct rules of constitutional law: one, that a woman has the right to choose to terminate a pregnancy; two, that such right may be overridden by the State's legitimate interests when the fetus is viable outside the womb. The latter is obviously distinct from the former. I would abandon that timing rule, but see no need in this case to consider the basic right.

The Court contends that it is impossible to address *Roe*'s conclusion that the Constitution protects the woman's right to abortion, without also addressing *Roe*'s rule that the State's interests are not constitutionally adequate to justify a ban on abortion until viability. See *ibid*. But we have partially overruled precedents before, see, *e.g.*, *United States* v. *Miller*, 471 U. S. 130, 142–144 (1985); *Daniels* v. *Williams*, 474 U. S. 327, 328–331 (1986); *Batson* v. *Kentucky*, 476 U. S. 79, 90–93 (1986), and certainly have never held that a distinct holding defining the contours of a constitutional right must be treated as part and parcel of the right itself.

Overruling the subsidiary rule is sufficient to resolve this case in Mississippi's favor. The law at issue allows abortions up through fifteen weeks, providing an adequate opportunity to exercise the right *Roe* protects. By the time a pregnant woman has reached that point, her pregnancy is well into the second trimester. Pregnancy tests are now inexpensive and accurate, and a woman ordinarily discovers she is pregnant by six weeks of gestation. See A. Branum & K. Ahrens, Trends in Timing of Pregnancy Awareness Among US Women, 21 Maternal & Child Health J. 715, 722

(2017). Almost all know by the end of the first trimester. Pregnancy Recognition 39. Safe and effective abortifacients, moreover, are now readily available, particularly during those early stages. See I. Adibi et al., Abortion, 22 Geo. J. Gender & L. 279, 303 (2021). Given all this, it is no surprise that the vast majority of abortions happen in the first trimester. See Centers for Disease Control and Prevention, Abortion Surveillance—United States 1 (2020). Presumably most of the remainder would also take place earlier if later abortions were not a legal option. Ample evidence thus suggests that a 15-week ban provides sufficient time, absent rare circumstances, for a woman "to decide for herself" whether to terminate her pregnancy. Webster, 492 U. S., at 520 (plurality opinion).*

TIT

Whether a precedent should be overruled is a question "entirely within the discretion of the court." Hertz v. Woodman, 218 U. S. 205, 212 (1910); see also Payne v. Tennessee, 501 U. S. 808, 828 (1991) (stare decisis is a "principle of policy"). In my respectful view, the sound exercise of that discretion should have led the Court to resolve the case on the narrower grounds set forth above, rather than overruling Roe and Casey entirely. The Court says there is no "principled basis" for this approach, ante, at 73, but in fact it is firmly grounded in basic principles of stare decisis and judicial restraint.

^{*}The majority contends that "nothing like [my approach] was recommended by either party." *Ante*, at 72. But as explained, Mississippi in fact pressed a similar argument in its filings before this Court. See Pet. for Cert. 15–26; Brief for Petitioners 5, 38–48 (urging the Court to reject the viability rule and reverse); Reply Brief 20–22 (same). The approach also finds support in prior opinions. See *Webster*, 492 U. S., at 518–521 (plurality opinion) (abandoning "key elements" of the *Roe* framework under *stare decisis* while declining to reconsider *Roe*'s holding that the Constitution protects the right to an abortion).

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The Court's decision to overrule *Roe* and *Casey* is a serious jolt to the legal system—regardless of how you view those cases. A narrower decision rejecting the misguided viability line would be markedly less unsettling, and nothing more is needed to decide this case.

Our cases say that the effect of overruling a precedent on reliance interests is a factor to consider in deciding whether to take such a step, and respondents argue that generations of women have relied on the right to an abortion in organizing their relationships and planning their futures. Brief for Respondents 36–41; see also *Casey*, 505 U. S., at 856 (making the same point). The Court questions whether these concerns are pertinent under our precedents, see *ante*, at 64–65, but the issue would not even arise with a decision rejecting only the viability line: It cannot reasonably be argued that women have shaped their lives in part on the assumption that they would be able to abort up to viability, as opposed to fifteen weeks.

In support of its holding, the Court cites three seminal constitutional decisions that involved overruling prior precedents: Brown v. Board of Education, 347 U. S. 483 (1954), West Virginia Bd. of Ed. v. Barnette, 319 U. S. 624 (1943), and West Coast Hotel Co. v. Parrish, 300 U.S. 379 (1937). See ante, at 40–41. The opinion in *Brown* was unanimous and eleven pages long; this one is neither. Barnette was decided only three years after the decision it overruled, three Justices having had second thoughts. And West Coast Hotel was issued against a backdrop of unprecedented economic despair that focused attention on the fundamental flaws of existing precedent. It also was part of a sea change in this Court's interpretation of the Constitution, "signal[ing] the demise of an entire line of important precedents," ante, at 40—a feature the Court expressly disclaims in today's decision, see ante, at 32, 66. None of these leading cases, in short, provides a template for what the Court does today.

The Court says we should consider whether to overrule Roe and Casey now, because if we delay we would be forced to consider the issue again in short order. See ante, at 76-77. There would be "turmoil" until we did so, according to the Court, because of existing state laws with "shorter deadlines or no deadline at all." Ante, at 76. But under the narrower approach proposed here, state laws outlawing abortion altogether would still violate binding precedent. And to the extent States have laws that set the cutoff date earlier than fifteen weeks, any litigation over that timeframe would proceed free of the distorting effect that the viability rule has had on our constitutional debate. The same could be true, for that matter, with respect to legislative consideration in the States. We would then be free to exercise our discretion in deciding whether and when to take up the issue, from a more informed perspective.

* * *

Both the Court's opinion and the dissent display a relentless freedom from doubt on the legal issue that I cannot share. I am not sure, for example, that a ban on terminating a pregnancy from the moment of conception must be treated the same under the Constitution as a ban after fifteen weeks. A thoughtful Member of this Court once counseled that the difficulty of a question "admonishes us to observe the wise limitations on our function and to confine ourselves to deciding only what is necessary to the disposition of the immediate case." Whitehouse v. Illinois Central R. Co., 349 U. S. 366, 372–373 (1955) (Frankfurter, J., for the Court). I would decide the question we granted review to answer—whether the previously recognized abortion right bars all abortion restrictions prior to viability, such that a ban on abortions after fifteen weeks of pregnancy is necessarily unlawful. The answer to that question is no, and there is no need to go further to decide this case.

I therefore concur only in the judgment.

SUPREME COURT OF THE UNITED STATES

No. 19-1392

THOMAS E. DOBBS, STATE HEALTH OFFICER OF THE MISSISSIPPI DEPARTMENT OF HEALTH, ET AL., PETITIONERS v. JACKSON WOMEN'S HEALTH ORGANIZATION, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

[June 24, 2022]

JUSTICE BREYER, JUSTICE SOTOMAYOR, and JUSTICE KAGAN, dissenting.

For half a century, Roe v. Wade, 410 U. S. 113 (1973), and Planned Parenthood of Southeastern Pa. v. Casey, 505 U. S. 833 (1992), have protected the liberty and equality of women. Roe held, and Casey reaffirmed, that the Constitution safeguards a woman's right to decide for herself whether to bear a child. Roe held, and Casey reaffirmed, that in the first stages of pregnancy, the government could not make that choice for women. The government could not control a woman's body or the course of a woman's life: It could not determine what the woman's future would be. See Casey, 505 U. S., at 853; Gonzales v. Carhart, 550 U. S. 124, 171–172 (2007) (Ginsburg, J., dissenting). Respecting a woman as an autonomous being, and granting her full equality, meant giving her substantial choice over this most personal and most consequential of all life decisions.

Roe and Casey well understood the difficulty and divisiveness of the abortion issue. The Court knew that Americans hold profoundly different views about the "moral[ity]" of "terminating a pregnancy, even in its earliest stage." Casey, 505 U. S., at 850. And the Court recognized that "the

State has legitimate interests from the outset of the pregnancy in protecting" the "life of the fetus that may become a child." *Id.*, at 846. So the Court struck a balance, as it often does when values and goals compete. It held that the State could prohibit abortions after fetal viability, so long as the ban contained exceptions to safeguard a woman's life or health. It held that even before viability, the State could regulate the abortion procedure in multiple and meaningful ways. But until the viability line was crossed, the Court held, a State could not impose a "substantial obstacle" on a woman's "right to elect the procedure" as she (not the government) thought proper, in light of all the circumstances and complexities of her own life. *Ibid*.

Today, the Court discards that balance. It says that from the very moment of fertilization, a woman has no rights to speak of. A State can force her to bring a pregnancy to term. even at the steepest personal and familial costs. An abortion restriction, the majority holds, is permissible whenever rational, the lowest level of scrutiny known to the law. And because, as the Court has often stated, protecting fetal life is rational, States will feel free to enact all manner of restrictions. The Mississippi law at issue here bars abortions after the 15th week of pregnancy. Under the majority's ruling, though, another State's law could do so after ten weeks, or five or three or one—or, again, from the moment of fertilization. States have already passed such laws, in anticipation of today's ruling. More will follow. Some States have enacted laws extending to all forms of abortion procedure, including taking medication in one's own home. They have passed laws without any exceptions for when the woman is the victim of rape or incest. Under those laws, a woman will have to bear her rapist's child or a young girl her father's—no matter if doing so will destroy her life. So too, after today's ruling, some States may compel women to carry to term a fetus with severe physical anomalies—for example, one afflicted with Tay-Sachs disease, sure to die

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within a few years of birth. States may even argue that a prohibition on abortion need make no provision for protecting a woman from risk of death or physical harm. Across a vast array of circumstances, a State will be able to impose its moral choice on a woman and coerce her to give birth to a child.

Enforcement of all these draconian restrictions will also be left largely to the States' devices. A State can of course impose criminal penalties on abortion providers, including lengthy prison sentences. But some States will not stop there. Perhaps, in the wake of today's decision, a state law will criminalize the woman's conduct too, incarcerating or fining her for daring to seek or obtain an abortion. And as Texas has recently shown, a State can turn neighbor against neighbor, enlisting fellow citizens in the effort to root out anyone who tries to get an abortion, or to assist another in doing so.

The majority tries to hide the geographically expansive effects of its holding. Today's decision, the majority says, permits "each State" to address abortion as it pleases. Ante, at 79. That is cold comfort, of course, for the poor woman who cannot get the money to fly to a distant State for a pro-Above all others, women lacking financial resources will suffer from today's decision. In any event, interstate restrictions will also soon be in the offing. After this decision, some States may block women from traveling out of State to obtain abortions, or even from receiving abortion medications from out of State. Some may criminalize efforts, including the provision of information or funding, to help women gain access to other States' abortion services. Most threatening of all, no language in today's decision stops the Federal Government from prohibiting abortions nationwide, once again from the moment of conception and without exceptions for rape or incest. If that happens, "the views of [an individual State's] citizens" will not matter. Ante, at 1. The challenge for a woman will be to finance a trip not to "New York [or] California" but to Toronto. *Ante*, at 4 (KAVANAUGH, J., concurring).

Whatever the exact scope of the coming laws, one result of today's decision is certain: the curtailment of women's rights, and of their status as free and equal citizens. Yesterday, the Constitution guaranteed that a woman confronted with an unplanned pregnancy could (within reasonable limits) make her own decision about whether to bear a child, with all the life-transforming consequences that act involves. And in thus safeguarding each woman's reproductive freedom, the Constitution also protected "[t]he ability of women to participate equally in [this Nation's] economic and social life." Casey, 505 U.S., at 856. But no longer. As of today, this Court holds, a State can always force a woman to give birth, prohibiting even the earliest abortions. A State can thus transform what, when freely undertaken, is a wonder into what, when forced, may be a nightmare. Some women, especially women of means, will find ways around the State's assertion of power. Others—those without money or childcare or the ability to take time off from work—will not be so fortunate. Maybe they will try an unsafe method of abortion, and come to physical harm, or even die. Maybe they will undergo pregnancy and have a child, but at significant personal or familial cost. At the least, they will incur the cost of losing control of their lives. The Constitution will, today's majority holds, provide no shield, despite its guarantees of liberty and equality for all.

And no one should be confident that this majority is done with its work. The right *Roe* and *Casey* recognized does not stand alone. To the contrary, the Court has linked it for decades to other settled freedoms involving bodily integrity, familial relationships, and procreation. Most obviously, the right to terminate a pregnancy arose straight out of the right to purchase and use contraception. See *Griswold* v. *Connecticut*, 381 U. S. 479 (1965); *Eisenstadt* v. *Baird*, 405 U. S. 438 (1972). In turn, those rights led, more recently,

to rights of same-sex intimacy and marriage. See Lawrence v. Texas, 539 U.S. 558 (2003); Obergefell v. Hodges, 576 U. S. 644 (2015). They are all part of the same constitutional fabric, protecting autonomous decisionmaking over the most personal of life decisions. The majority (or to be more accurate, most of it) is eager to tell us today that nothing it does "cast[s] doubt on precedents that do not concern abortion." Ante, at 66; cf. ante, at 3 (THOMAS, J., concurring) (advocating the overruling of Griswold, Lawrence, and Obergefell). But how could that be? The lone rationale for what the majority does today is that the right to elect an abortion is not "deeply rooted in history": Not until Roe, the majority argues, did people think abortion fell within the Constitution's guarantee of liberty. Ante, at 32. The same could be said, though, of most of the rights the majority claims it is not tampering with. The majority could write just as long an opinion showing, for example, that until the mid-20th century, "there was no support in American law for a constitutional right to obtain [contraceptives]." *Ante*, at 15. So one of two things must be true. Either the majority does not really believe in its own reasoning. Or if it does, all rights that have no history stretching back to the mid-19th century are insecure. Either the mass of the majority's opinion is hypocrisy, or additional constitutional rights are under threat. It is one or the other.

One piece of evidence on that score seems especially salient: The majority's cavalier approach to overturning this Court's precedents. *Stare decisis* is the Latin phrase for a foundation stone of the rule of law: that things decided should stay decided unless there is a very good reason for change. It is a doctrine of judicial modesty and humility. Those qualities are not evident in today's opinion. The majority has no good reason for the upheaval in law and society it sets off. *Roe* and *Casey* have been the law of the land for decades, shaping women's expectations of their choices when an unplanned pregnancy occurs. Women have relied

on the availability of abortion both in structuring their relationships and in planning their lives. The legal framework *Roe* and *Casey* developed to balance the competing interests in this sphere has proved workable in courts across the country. No recent developments, in either law or fact, have eroded or cast doubt on those precedents. Nothing, in short, has changed. Indeed, the Court in Casey already found all of that to be true. Casey is a precedent about precedent. It reviewed the same arguments made here in support of overruling *Roe*, and it found that doing so was not warranted. The Court reverses course today for one reason and one reason only: because the composition of this Court has changed. Stare decisis, this Court has often said, "contributes to the actual and perceived integrity of the judicial process" by ensuring that decisions are "founded in the law rather than in the proclivities of individuals." Payne v. Tennessee, 501 U.S. 808, 827 (1991); Vasquez v. Hillery, 474 U. S. 254, 265 (1986). Today, the proclivities of individuals rule. The Court departs from its obligation to faithfully and impartially apply the law. We dissent.

Ι

We start with *Roe* and *Casey*, and with their deep connections to a broad swath of this Court's precedents. To hear the majority tell the tale, *Roe* and *Casey* are aberrations: They came from nowhere, went nowhere—and so are easy to excise from this Nation's constitutional law. That is not true. After describing the decisions themselves, we explain how they are rooted in—and themselves led to—other rights giving individuals control over their bodies and their most personal and intimate associations. The majority does not wish to talk about these matters for obvious reasons; to do so would both ground *Roe* and *Casey* in this Court's precedents and reveal the broad implications of today's decision. But the facts will not so handily disappear. *Roe* and *Casey* were from the beginning, and are even more now, embedded

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in core constitutional concepts of individual freedom, and of the equal rights of citizens to decide on the shape of their lives. Those legal concepts, one might even say, have gone far toward defining what it means to be an American. For in this Nation, we do not believe that a government controlling all private choices is compatible with a free people. So we do not (as the majority insists today) place everything within "the reach of majorities and [government] officials." West Virginia Bd. of Ed. v. Barnette, 319 U. S. 624, 638 (1943). We believe in a Constitution that puts some issues off limits to majority rule. Even in the face of public opposition, we uphold the right of individuals—yes, including women—to make their own choices and chart their own futures. Or at least, we did once.

Α

Some half-century ago, Roe struck down a state law making it a crime to perform an abortion unless its purpose was to save a woman's life. The *Roe* Court knew it was treading on difficult and disputed ground. It understood that different people's "experiences," "values," and "religious training" and beliefs led to "opposing views" about abortion. 410 U. S., at 116. But by a 7-to-2 vote, the Court held that in the earlier stages of pregnancy, that contested and contestable choice must belong to a woman, in consultation with her family and doctor. The Court explained that a long line of precedents, "founded in the Fourteenth Amendment's concept of personal liberty," protected individual decisionmaking related to "marriage, procreation, contraception, family relationships, and child rearing and education." *Id.*, at 152–153 (citations omitted). For the same reasons, the Court held, the Constitution must protect "a woman's decision whether or not to terminate her pregnancy." Id., at 153. The Court recognized the myriad ways bearing a child can alter the "life and future" of a woman and other members of her family. *Ibid*. A State could not, "by adopting one theory of life," override all "rights of the pregnant woman." *Id.*, at 162.

At the same time, though, the Court recognized "valid interest[s]" of the State "in regulating the abortion decision." *Id.*, at 153. The Court noted in particular "important interests" in "protecting potential life," "maintaining medical standards," and "safeguarding [the] health" of the woman. *Id.*, at 154. No "absolut[ist]" account of the woman's right could wipe away those significant state claims. *Ibid.*

The Court therefore struck a balance, turning on the stage of the pregnancy at which the abortion would occur. The Court explained that early on, a woman's choice must prevail, but that "at some point the state interests" become "dominant." *Id.*, at 155. It then set some guideposts. In the first trimester of pregnancy, the State could not interfere at all with the decision to terminate a pregnancy. At any time after that point, the State could regulate to protect the pregnant woman's health, such as by insisting that abortion providers and facilities meet safety requirements. And after the fetus's viability—the point when the fetus "has the capability of meaningful life outside the mother's womb"—the State could ban abortions, except when necessary to preserve the woman's life or health. *Id.*, at 163–164.

In the 20 years between *Roe* and *Casey*, the Court expressly reaffirmed *Roe* on two occasions, and applied it on many more. Recognizing that "arguments [against *Roe*] continue to be made," we responded that the doctrine of stare decisis "demands respect in a society governed by the rule of law." *Akron* v. *Akron Center for Reproductive Health, Inc.*, 462 U. S. 416, 419–420 (1983). And we avowed that the "vitality" of "constitutional principles cannot be allowed to yield simply because of disagreement with them." *Thornburgh* v. *American College of Obstetricians and Gynecologists*, 476 U. S. 747, 759 (1986). So the Court, over and

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over, enforced the constitutional principles Roe had declared. See, e.g., Ohio v. Akron Center for Reproductive Health, 497 U. S. 502 (1990); Hodgson v. Minnesota, 497 U. S. 417 (1990); Simopoulos v. Virginia, 462 U. S. 506 (1983); Planned Parenthood Assn. of Kansas City, Mo., Inc. v. Ashcroft, 462 U. S. 476 (1983); H. L. v. Matheson, 450 U. S. 398 (1981); Bellotti v. Baird, 443 U. S. 622 (1979); Planned Parenthood of Central Mo. v. Danforth, 428 U. S. 52 (1976).

Then, in *Casey*, the Court considered the matter anew, and again upheld *Roe*'s core precepts. *Casey* is in significant measure a precedent about the doctrine of precedent—until today, one of the Court's most important. But we leave for later that aspect of the Court's decision. The key thing now is the substantive aspect of the Court's considered conclusion that "the essential holding of *Roe* v. *Wade* should be retained and once again reaffirmed." 505 U.S., at 846.

Central to that conclusion was a full-throated restatement of a woman's right to choose. Like Roe, Casey grounded that right in the Fourteenth Amendment's guarantee of "liberty." That guarantee encompasses realms of conduct not specifically referenced in the Constitution: "Marriage is mentioned nowhere" in that document, yet the Court was "no doubt correct" to protect the freedom to marry "against state interference." 505 U.S., at 847-848. And the guarantee of liberty encompasses conduct today that was not protected at the time of the Fourteenth Amendment. See id., at 848. "It is settled now," the Court said—though it was not always so—that "the Constitution places limits on a State's right to interfere with a person's most basic decisions about family and parenthood, as well as bodily integrity." Id., at 849 (citations omitted); see id., at 851 (similarly describing the constitutional protection given to "personal decisions relating to marriage, procreation, contraception, [and] family relationships"). Especially

important in this web of precedents protecting an individual's most "personal choices" were those guaranteeing the right to contraception. *Ibid.*; see *id.*, at 852–853. In those cases, the Court had recognized "the right of the individual" to make the vastly consequential "decision whether to bear" a child. *Id.*, at 851 (emphasis deleted). So too, *Casey* reasoned, the liberty clause protects the decision of a woman confronting an unplanned pregnancy. Her decision about abortion was central, in the same way, to her capacity to chart her life's course. See *id.*, at 853.

In reaffirming the right Roe recognized, the Court took full account of the diversity of views on abortion, and the importance of various competing state interests. Some Americans, the Court stated, "deem [abortion] nothing short of an act of violence against innocent human life." 505 U. S., at 852. And each State has an interest in "the protection of potential life"—as Roe itself had recognized. 505 U. S., at 871 (plurality opinion). On the one hand, that interest was not conclusive. The State could not "resolve" the "moral and spiritual" questions raised by abortion in "such a definitive way that a woman lacks all choice in the matter." Id., at 850 (majority opinion). It could not force her to bear the "pain" and "physical constraints" of "carr[ying] a child to full term" when she would have chosen an early abortion. Id., at 852. But on the other hand, the State had, as Roe had held, an exceptionally significant interest in disallowing abortions in the later phase of a pregnancy. And it had an ever-present interest in "ensur[ing] that the woman's choice is informed" and in presenting the case for "choos[ing] childbirth over abortion." 505 U.S., at 878 (plurality opinion).

So *Casey* again struck a balance, differing from *Roe*'s in only incremental ways. It retained *Roe*'s "central holding" that the State could bar abortion only after viability. 505 U. S., at 860 (majority opinion). The viability line, *Casey* thought, was "more workable" than any other in marking

the place where the woman's liberty interest gave way to a State's efforts to preserve potential life. Id., at 870 (plurality opinion). At that point, a "second life" was capable of "independent existence." *Ibid*. If the woman even by then had not acted, she lacked adequate grounds to object to "the State's intervention on [the developing child's] behalf." *Ibid.* At the same time, Casey decided, based on two decades of experience, that the Roe framework did not give States sufficient ability to regulate abortion prior to viability. In that period, Casey now made clear, the State could regulate not only to protect the woman's health but also to "promot[e] prenatal life." 505 U.S., at 873 (plurality opinion). In particular, the State could ensure informed choice and could try to promote childbirth. See id., at 877–878. But the State still could not place an "undue burden"—or "substantial obstacle"—"in the path of a woman seeking an abortion." Id., at 878. Prior to viability, the woman, consistent with the constitutional "meaning of liberty," must "retain the ultimate control over her destiny and her body." Id., at 869.

We make one initial point about this analysis in light of the majority's insistence that *Roe* and *Casey*, and we in defending them, are dismissive of a "State's interest in protecting prenatal life." *Ante*, at 38. Nothing could get those decisions more wrong. As just described, *Roe* and *Casey* invoked powerful state interests in that protection, operative at every stage of the pregnancy and overriding the woman's liberty after viability. The strength of those state interests is exactly why the Court allowed greater restrictions on the abortion right than on other rights deriving from the Fourteenth Amendment.¹ But what *Roe* and *Casey* also recognized—which today's majority does not—is that a woman's

¹For this reason, we do not understand the majority's view that our analogy between the right to an abortion and the rights to contraception and same-sex marriage shows that we think "[t]he Constitution does not permit the States to regard the destruction of a 'potential life' as a matter

freedom and equality are likewise involved. That fact—the presence of countervailing interests—is what made the abortion question hard, and what necessitated balancing. The majority scoffs at that idea, castigating us for "repeatedly prais[ing] the 'balance'" the two cases arrived at (with the word "balance" in scare quotes). Ante, at 38. To the majority "balance" is a dirty word, as moderation is a foreign concept. The majority would allow States to ban abortion from conception onward because it does not think forced childbirth at all implicates a woman's rights to equality and freedom. Today's Court, that is, does not think there is anything of constitutional significance attached to a woman's control of her body and the path of her life. Roe and Casey thought that one-sided view misguided. In some sense, that is the difference in a nutshell between our precedents and the majority opinion. The constitutional regime we have lived in for the last 50 years recognized competing interests, and sought a balance between them. The constitutional regime we enter today erases the woman's interest and recognizes only the State's (or the Federal Government's).

В

The majority makes this change based on a single question: Did the reproductive right recognized in *Roe* and *Casey*

of any significance." *Ante*, at 38. To the contrary. The liberty interests underlying those rights are, as we will describe, quite similar. See *infra*, at 22–24. But only in the sphere of abortion is the state interest in protecting potential life involved. So only in that sphere, as both *Roe* and *Casey* recognized, may a State impinge so far on the liberty interest (barring abortion after viability and discouraging it before). The majority's failure to understand this fairly obvious point stems from its rejection of the idea of balancing interests in this (or maybe in any) constitutional context. Cf. *New York State Rifle & Pistol Assn., Inc.* v. *Bruen*, 597 U. S. ____, ____ (2022) (slip op., at 8, 15–17). The majority thinks that a woman has *no* liberty or equality interest in the decision to bear a child, so a State's interest in protecting fetal life necessarily prevails.

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exist in "1868, the year when the Fourteenth Amendment was ratified"? *Ante*, at 23. The majority says (and with this much we agree) that the answer to this question is no: In 1868, there was no nationwide right to end a pregnancy, and no thought that the Fourteenth Amendment provided one.

Of course, the majority opinion refers as well to some later and earlier history. On the one side of 1868, it goes back as far as the 13th (the 13th!) century. See ante, at 17. But that turns out to be wheel-spinning. First, it is not clear what relevance such early history should have, even to the majority. See New York State Rifle & Pistol Assn., Inc. v. Bruen, 597 U. S. ____, ___ (2022) (slip op., at 26) ("Historical evidence that long predates [ratification] may not illuminate the scope of the right"). If the early history obviously supported abortion rights, the majority would no doubt say that only the views of the Fourteenth Amendment's ratifiers are germane. See ibid. (It is "better not to go too far back into antiquity," except if olden "law survived to become our Founders' law"). Second—and embarrassingly for the majority—early law in fact does provide some support for abortion rights. Common-law authorities did not treat abortion as a crime before "quickening"—the point when the fetus moved in the womb.² And early American law followed the common-law rule.³ So the criminal law of that early time might be taken as roughly consonant with

²See, *e.g.*, 1 W. Blackstone, Commentaries on the Laws of England 129–130 (7th ed. 1775) (Blackstone); E. Coke, Institutes of the Laws of England 50 (1644).

³See J. Mohr, Abortion in America: The Origins and Evolution of National Policy, 1800–1900, pp. 3–4 (1978). The majority offers no evidence to the contrary—no example of a founding-era law making prequickening abortion a crime (except when a woman died). See *ante*, at 20–21. And even in the mid-19th century, more than 10 States continued to allow pre-quickening abortions. See Brief for American Historical Association et al. as *Amici Curiae* 27, and n. 14.

Roe's and Casey's different treatment of early and late abortions. Better, then, to move forward in time. On the other side of 1868, the majority occasionally notes that many States barred abortion up to the time of Roe. See ante, at 24, 36. That is convenient for the majority, but it is window dressing. As the same majority (plus one) just informed us, "post-ratification adoption or acceptance of laws that are inconsistent with the original meaning of the constitutional text obviously cannot overcome or alter that text." New York State Rifle & Pistol Assn., Inc., 597 U. S., at _____ (slip op., at 27–28). Had the pre-Roe liberalization of abortion laws occurred more quickly and more widely in the 20th century, the majority would say (once again) that only the ratifiers' views are germane.

The majority's core legal postulate, then, is that we in the 21st century must read the Fourteenth Amendment just as its ratifiers did. And that is indeed what the majority emphasizes over and over again. See *ante*, at 47 ("[T]he most important historical fact [is] how the States regulated abortion when the Fourteenth Amendment was adopted"); see also *ante*, at 5, 16, and n. 24, 23, 25, 28. If the ratifiers did not understand something as central to freedom, then neither can we. Or said more particularly: If those people did not understand reproductive rights as part of the guarantee of liberty conferred in the Fourteenth Amendment, then those rights do not exist.

As an initial matter, note a mistake in the just preceding sentence. We referred there to the "people" who ratified the Fourteenth Amendment: What rights did those "people" have in their heads at the time? But, of course, "people" did not ratify the Fourteenth Amendment. Men did. So it is perhaps not so surprising that the ratifiers were not perfectly attuned to the importance of reproductive rights for women's liberty, or for their capacity to participate as equal members of our Nation. Indeed, the ratifiers—both in 1868 and when the original Constitution was approved in 1788—

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did not understand women as full members of the community embraced by the phrase "We the People." In 1868, the first wave of American feminists were explicitly told—of course by men—that it was not their time to seek constitutional protections. (Women would not get even the vote for another half-century.) To be sure, most women in 1868 also had a foreshortened view of their rights: If most men could not then imagine giving women control over their bodies, most women could not imagine having that kind of autonomy. But that takes away nothing from the core point. Those responsible for the original Constitution, including the Fourteenth Amendment, did not perceive women as equals, and did not recognize women's rights. When the majority says that we must read our foundational charter as viewed at the time of ratification (except that we may also check it against the Dark Ages), it consigns women to second-class citizenship.

Casey itself understood this point, as will become clear. See infra, at 23–24. It recollected with dismay a decision this Court issued just five years after the Fourteenth Amendment's ratification, approving a State's decision to deny a law license to a woman and suggesting as well that a woman had no legal status apart from her husband. See 505 U. S., at 896–897 (majority opinion) (citing *Bradwell* v. State, 16 Wall. 130 (1873)). "There was a time," Casey explained, when the Constitution did not protect "men and women alike." 505 U.S., at 896. But times had changed. A woman's place in society had changed, and constitutional law had changed along with it. The relegation of women to inferior status in either the public sphere or the family was "no longer consistent with our understanding" of the Constitution. Id., at 897. Now, "[t]he Constitution protects all individuals, male or female," from "the abuse of governmental power" or "unjustified state interference." Id., at 896, 898.

So how is it that, as *Casey* said, our Constitution, read

now, grants rights to women, though it did not in 1868? How is it that our Constitution subjects discrimination against them to heightened judicial scrutiny? How is it that our Constitution, through the Fourteenth Amendment's liberty clause, guarantees access to contraception (also not legally protected in 1868) so that women can decide for themselves whether and when to bear a child? How is it that until today, that same constitutional clause protected a woman's right, in the event contraception failed, to end a pregnancy in its earlier stages?

The answer is that this Court has rejected the majority's pinched view of how to read our Constitution. "The Founders," we recently wrote, "knew they were writing a document designed to apply to ever-changing circumstances over centuries." NLRB v. Noel Canning, 573 U.S. 513, 533–534 (2014). Or in the words of the great Chief Justice John Marshall, our Constitution is "intended to endure for ages to come," and must adapt itself to a future "seen dimly," if at all. McCulloch v. Maryland, 4 Wheat. 316, 415 (1819). That is indeed why our Constitution is written as it is. The Framers (both in 1788 and 1868) understood that the world changes. So they did not define rights by reference to the specific practices existing at the time. Instead, the Framers defined rights in general terms, to permit future evolution in their scope and meaning. And over the course of our history, this Court has taken up the Framers' invitation. It has kept true to the Framers' principles by applying them in new ways, responsive to new societal understandings and conditions.

Nowhere has that approach been more prevalent than in construing the majestic but open-ended words of the Fourteenth Amendment—the guarantees of "liberty" and "equality" for all. And nowhere has that approach produced prouder moments, for this country and the Court. Consider an example *Obergefell* used a few years ago. The Court

there confronted a claim, based on Washington v. Glucksberg, 521 U. S. 702 (1997), that the Fourteenth Amendment "must be defined in a most circumscribed manner, with central reference to specific historical practices"—exactly the view today's majority follows. *Obergefell*, 576 U.S., at 671. And the Court specifically rejected that view.⁴ In doing so, the Court reflected on what the proposed, historically circumscribed approach would have meant for interracial marriage. See *ibid*. The Fourteenth Amendment's ratifiers did not think it gave black and white people a right to marry each other. To the contrary, contemporaneous practice deemed that act quite as unprotected as abortion. Yet the Court in Loving v. Virginia, 388 U.S. 1 (1967), read the Fourteenth Amendment to embrace the Lovings' union. If, Obergefell explained, "rights were defined by who exercised them in the past, then received practices could serve as their own continued justification"—even when they conflict with "liberty" and "equality" as later and more broadly understood. 576 U.S., at 671. The Constitution does not freeze for all time the original view of what those rights guarantee, or how they apply.

That does not mean anything goes. The majority wishes people to think there are but two alternatives: (1) accept the original applications of the Fourteenth Amendment and no others, or (2) surrender to judges' "own ardent views," ungrounded in law, about the "liberty that Americans should enjoy." *Ante*, at 14. At least, that idea is what the majority *sometimes* tries to convey. At other times, the majority (or, rather, most of it) tries to assure the public that it has no designs on rights (for example, to contraception) that arose only in the back half of the 20th century—in other words,

⁴The majority ignores that rejection. See *ante*, at 5, 13, 36. But it is unequivocal: The *Glucksberg* test, *Obergefell* said, "may have been appropriate" in considering physician-assisted suicide, but "is inconsistent with the approach this Court has used in discussing other fundamental rights, including marriage and intimacy." 576 U. S., at 671.

that it is happy to pick and choose, in accord with individual preferences. See ante, at 32, 66, 71–72; ante, at 10 (KAVANAUGH, J., concurring); but see ante, at 3 (THOMAS, J., concurring). But that is a matter we discuss later. See *infra*, at 24–29. For now, our point is different: It is that applications of liberty and equality can evolve while remaining grounded in constitutional principles, constitutional history, and constitutional precedents. The second Justice Harlan discussed how to strike the right balance when he explained why he would have invalidated a State's ban on contraceptive use. Judges, he said, are not "free to roam where unguided speculation might take them." Poe v. Ullman, 367 U. S. 497, 542 (1961) (dissenting opinion). Yet they also must recognize that the constitutional "tradition" of this country is not captured whole at a single moment. Rather, its meaning gains content from the long sweep of our history and from successive judicial precedents—each looking to the last and each seeking to apply the Constitution's most fundamental commitments to new conditions. That is why Americans, to go back to Obergefell's example, have a right to marry across racial lines. And it is why, to go back to Justice Harlan's case, Americans have a right to use contraceptives so they can choose for themselves whether to have children.

All that is what *Casey* understood. *Casey* explicitly rejected the present majority's method. "[T]he specific practices of States at the time of the adoption of the Fourteenth Amendment," *Casey* stated, do not "mark[] the outer limits of the substantive sphere of liberty which the Fourteenth Amendment protects." 505 U. S., at 848.⁵ To hold otherwise—as the majority does today—"would be inconsistent

⁵In a perplexing paragraph in its opinion, the majority declares that it need not say whether that statement from *Casey* is true. See *ante*, at 32–33. But how could that be? Has not the majority insisted for the prior 30 or so pages that the "specific practice[]" respecting abortion at the

with our law." Id., at 847. Why? Because the Court has "vindicated [the] principle" over and over that (no matter the sentiment in 1868) "there is a realm of personal liberty which the government may not enter"—especially relating to "bodily integrity" and "family life." Id., at 847, 849, 851. Casey described in detail the Court's contraception cases. See id., at 848–849, 851–853. It noted decisions protecting the right to marry, including to someone of another race. See id., at 847–848 ("[I]nterracial marriage was illegal in most States in the 19th century, but the Court was no doubt correct in finding it to be an aspect of liberty protected against state interference"). In reviewing decades and decades of constitutional law, Casey could draw but one conclusion: Whatever was true in 1868, "[i]t is settled now, as it was when the Court heard arguments in Roe v. Wade, that the Constitution places limits on a State's right to interfere with a person's most basic decisions about family and parenthood." Id., at 849.

And that conclusion still held good, until the Court's intervention here. It was settled at the time of *Roe*, settled at the time of *Casey*, and settled yesterday that the Constitution places limits on a State's power to assert control over an individual's body and most personal decisionmaking. A multitude of decisions supporting that principle led to *Roe*'s recognition and *Casey*'s reaffirmation of the right to choose; and *Roe* and *Casey* in turn supported additional protections for intimate and familial relations. The majority has em-

time of the Fourteenth Amendment precludes its recognition as a constitutional right? *Ante*, at 33. It has. And indeed, it has given no other reason for overruling *Roe* and *Casey*. *Ante*, at 15–16. We are not mindreaders, but here is our best guess as to what the majority means. It says next that "[a]bortion is nothing new." *Ante*, at 33. So apparently, the Fourteenth Amendment might provide protection for things wholly unknown in the 19th century; maybe one day there could be constitutional protection for, oh, time travel. But as to anything that was known back then (such as abortion or contraception), no such luck.

barrassingly little to say about those precedents. It (literally) rattles them off in a single paragraph; and it implies that they have nothing to do with each other, or with the right to terminate an early pregnancy. See *ante*, at 31–32 (asserting that recognizing a relationship among them, as addressing aspects of personal autonomy, would ineluctably "license fundamental rights" to illegal "drug use [and] prostitution"). But that is flat wrong. The Court's precedents about bodily autonomy, sexual and familial relations, and procreation are all interwoven—all part of the fabric of our constitutional law, and because that is so, of our lives. Especially women's lives, where they safeguard a right to self-determination.

And eliminating that right, we need to say before further describing our precedents, is not taking a "neutral" position, as JUSTICE KAVANAUGH tries to argue. Ante, at 2-3, 5, 7, 11–12 (concurring opinion). His idea is that neutrality lies in giving the abortion issue to the States, where some can go one way and some another. But would he say that the Court is being "scrupulously neutral" if it allowed New York and California to ban all the guns they want? Ante, at 3. If the Court allowed some States to use unanimous juries and others not? If the Court told the States: Decide for yourselves whether to put restrictions on church attendance? We could go on—and in fact we will. Suppose JUSTICE KAVANAUGH were to say (in line with the majority opinion) that the rights we just listed are more textually or historically grounded than the right to choose. What, then, of the right to contraception or same-sex marriage? Would it be "scrupulously neutral" for the Court to eliminate those rights too? The point of all these examples is that when it comes to rights, the Court does not act "neutrally" when it leaves everything up to the States. Rather, the Court acts neutrally when it protects the right against all comers. And to apply that point to the case here: When the Court decimates a right women have held for 50 years, the Court is

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not being "scrupulously neutral." It is instead taking sides: against women who wish to exercise the right, and for States (like Mississippi) that want to bar them from doing so. JUSTICE KAVANAUGH cannot obscure that point by appropriating the rhetoric of even-handedness. His position just is what it is: A brook-no-compromise refusal to recognize a woman's right to choose, from the first day of a pregnancy. And that position, as we will now show, cannot be squared with this Court's longstanding view that women indeed have rights (whatever the state of the world in 1868) to make the most personal and consequential decisions about their bodies and their lives.

Consider first, then, the line of this Court's cases protecting "bodily integrity." Casey, 505 U.S., at 849. "No right," in this Court's time-honored view, "is held more sacred, or is more carefully guarded," than "the right of every individual to the possession and control of his own person." Union Pacific R. Co. v. Botsford, 141 U.S. 250, 251 (1891); see Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261, 269 (1990) (Every adult "has a right to determine what shall be done with his own body"). Or to put it more simply: Everyone, including women, owns their own bodies. So the Court has restricted the power of government to interfere with a person's medical decisions or compel her to undergo medical procedures or treatments. See, e.g., Winston v. Lee, 470 U. S. 753, 766–767 (1985) (forced surgery); Rochin v. California, 342 U.S. 165, 166, 173-174 (1952) (forced stomach pumping); Washington v. Harper, 494 U.S. 210, 229, 236 (1990) (forced administration of antipsychotic drugs).

Casey recognized the "doctrinal affinity" between those precedents and Roe. 505 U. S., at 857. And that doctrinal affinity is born of a factual likeness. There are few greater incursions on a body than forcing a woman to complete a pregnancy and give birth. For every woman, those experiences involve all manner of physical changes, medical treatments (including the possibility of a cesarean section), and

medical risk. Just as one example, an American woman is 14 times more likely to die by carrying a pregnancy to term than by having an abortion. See *Whole Woman's Health* v. *Hellerstedt*, 579 U. S. 582, 618 (2016). That women happily undergo those burdens and hazards of their own accord does not lessen how far a State impinges on a woman's body when it compels her to bring a pregnancy to term. And for some women, as *Roe* recognized, abortions are medically necessary to prevent harm. See 410 U. S., at 153. The majority does not say—which is itself ominous—whether a State may prevent a woman from obtaining an abortion when she and her doctor have determined it is a needed medical treatment.

So too, Roe and Casey fit neatly into a long line of decisions protecting from government intrusion a wealth of private choices about family matters, child rearing, intimate relationships, and procreation. See Casey, 505 U.S., at 851, 857; Roe, 410 U. S., at 152–153; see also ante, at 31–32 (listing the myriad decisions of this kind that *Casey* relied on). Those cases safeguard particular choices about whom to marry; whom to have sex with; what family members to live with; how to raise children—and crucially, whether and when to have children. In varied cases, the Court explained that those choices—"the most intimate and personal" a person can make—reflect fundamental aspects of personal identity; they define the very "attributes of personhood." Casey, 505 U.S., at 851. And they inevitably shape the nature and future course of a person's life (and often the lives of those closest to her). So, the Court held, those choices belong to the individual, and not the government. That is the essence of what liberty requires.

And liberty may require it, this Court has repeatedly said, even when those living in 1868 would not have recognized the claim—because they would not have seen the person making it as a full-fledged member of the community. Throughout our history, the sphere of protected liberty has

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expanded, bringing in individuals formerly excluded. In that way, the constitutional values of liberty and equality go hand in hand; they do not inhabit the hermetically sealed containers the majority portrays. Compare Obergefell, 576 U. S., at 672–675, with *ante*, at 10–11. So before *Roe* and Casey, the Court expanded in successive cases those who could claim the right to marry—though their relationships would have been outside the law's protection in the mid-19th century. See, e.g., Loving, 388 U.S. 1 (interracial couples); Turner v. Safley, 482 U. S. 78 (1987) (prisoners); see also, e.g., Stanley v. Illinois, 405 U. S. 645, 651–652 (1972) (offering constitutional protection to untraditional "family unit[s]"). And after Roe and Casey, of course, the Court continued in that vein. With a critical stop to hold that the Fourteenth Amendment protected same-sex intimacy, the Court resolved that the Amendment also conferred on same-sex couples the right to marry. See Lawrence, 539 U. S. 558; Obergefell, 576 U. S. 644. In considering that question, the Court held, "[h]istory and tradition," especially as reflected in the course of our precedent, "guide and discipline [the] inquiry." Id., at 664. But the sentiments of 1868 alone do not and cannot "rule the present." *Ibid*.

Casey similarly recognized the need to extend the constitutional sphere of liberty to a previously excluded group. The Court then understood, as the majority today does not, that the men who ratified the Fourteenth Amendment and wrote the state laws of the time did not view women as full and equal citizens. See *supra*, at 15. A woman then, *Casey* wrote, "had no legal existence separate from her husband." 505 U. S., at 897. Women were seen only "as the center of home and family life," without "full and independent legal status under the Constitution." *Ibid.* But that could not be true any longer: The State could not now insist on the historically dominant "vision of the woman's role." *Id.*, at 852. And equal citizenship, *Casey* realized, was inescapably con-

nected to reproductive rights. "The ability of women to participate equally" in the "life of the Nation"—in all its economic, social, political, and legal aspects—"has been facilitated by their ability to control their reproductive lives." *Id.*, at 856. Without the ability to decide whether and when to have children, women could not—in the way men took for granted—determine how they would live their lives, and how they would contribute to the society around them.

For much that reason, Casey made clear that the precedents Roe most closely tracked were those involving contraception. Over the course of three cases, the Court had held that a right to use and gain access to contraception was part of the Fourteenth Amendment's guarantee of liberty. See Griswold, 381 U. S. 479; Eisenstadt, 405 U. S. 438; Carey v. Population Services Int'l, 431 U.S. 678 (1977). That clause, we explained, necessarily conferred a right "to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child." Eisenstadt, 405 U.S., at 453; see Carey, 431 U.S., at 684–685. Casey saw Roe as of a piece: In "critical respects the abortion decision is of the same character." 505 U.S., at 852. "[R]easonable people," the Court noted, could also oppose contraception; and indeed, they could believe that "some forms of contraception" similarly implicate a concern with "potential life." Id., at 853, 859. Yet the views of others could not automatically prevail against a woman's right to control her own body and make her own choice about whether to bear, and probably to raise, a child. When an unplanned pregnancy is involved because either contraception or abortion is outlawed—"the liberty of the woman is at stake in a sense unique to the human condition." Id., at 852. No State could undertake to resolve the moral questions raised "in such a definitive way" as to deprive a woman of all choice. *Id.*, at 850.

Faced with all these connections between *Roe/Casey* and judicial decisions recognizing other constitutional rights,

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the majority tells everyone not to worry. It can (so it says) neatly extract the right to choose from the constitutional edifice without affecting any associated rights. (Think of someone telling you that the Jenga tower simply will not collapse.) Today's decision, the majority first says, "does not undermine" the decisions cited by Roe and Casey—the ones involving "marriage, procreation, contraception, [and] family relationships"—"in any way." Ante, at 32; Casey, 505 U. S., at 851. Note that this first assurance does not extend to rights recognized after *Roe* and *Casey*, and partly based on them—in particular, rights to same-sex intimacy and marriage. See *supra*, at 23.6 On its later tries, though, the majority includes those too: "Nothing in this opinion should be understood to cast doubt on precedents that do not concern abortion." Ante, at 66; see ante, at 71–72. That right is unique, the majority asserts, "because [abortion] terminates life or potential life." Ante, at 66 (internal quotation marks omitted); see ante, at 32, 71-72. So the majority depicts today's decision as "a restricted railroad ticket, good for this day and train only." Smith v. Allwright, 321 U.S. 649, 669 (1944) (Roberts, J., dissenting). Should the audience for these too-much-repeated protestations be duly satisfied? We think not.

The first problem with the majority's account comes from JUSTICE THOMAS's concurrence—which makes clear he is not with the program. In saying that nothing in today's opinion casts doubt on non-abortion precedents, JUSTICE THOMAS explains, he means only that they are not at issue

⁶And note, too, that the author of the majority opinion recently joined a statement, written by another member of the majority, lamenting that *Obergefell* deprived States of the ability "to resolve th[e] question [of same-sex marriage] through legislation." *Davis* v. *Ermold*, 592 U. S. ___, __ (2020) (statement of Thomas, J.) (slip op., at 1). That might sound familiar. Cf. *ante*, at 44 (lamenting that *Roe* "short-circuited the democratic process"). And those two Justices hardly seemed content to let the matter rest: The Court, they said, had "created a problem that only it can fix." *Davis*, 592 U. S., at ___ (slip op., at 4).

in this very case. See *ante*, at 7 ("[T]his case does not present the opportunity to reject" those precedents). But he lets us know what he wants to do when they are. "[I]n future cases," he says, "we should reconsider all of this Court's substantive due process precedents, including *Griswold*, *Lawrence*, and *Obergefell*." *Ante*, at 3; see also *supra*, at 25, and n. 6. And when we reconsider them? Then "we have a duty" to "overrul[e] these demonstrably erroneous decisions." *Ante*, at 3. So at least one Justice is planning to use the ticket of today's decision again and again and again.

Even placing the concurrence to the side, the assurance in today's opinion still does not work. Or at least that is so if the majority is serious about its sole reason for overturning *Roe* and *Casey*: the legal status of abortion in the 19th century. Except in the places quoted above, the state interest in protecting fetal life plays no part in the majority's analysis. To the contrary, the majority takes pride in not expressing a view "about the status of the fetus." *Ante*, at 65; see *ante*, at 32 (aligning itself with *Roe*'s and *Casey*'s stance of not deciding whether life or potential life is involved); *ante*, at 38–39 (similar). The majority's departure from *Roe* and *Casey* rests instead—and only—on whether a woman's decision to end a pregnancy involves any Fourteenth Amendment liberty interest (against which *Roe* and *Casey* balanced the state interest in preserving fetal life).

⁷Indulge a few more words about this point. The majority had a choice of two different ways to overrule *Roe* and *Casey*. It could claim that those cases underrated the State's interest in fetal life. Or it could claim that they overrated a woman's constitutional liberty interest in choosing an abortion. (Or both.) The majority here rejects the first path, and we can see why. Taking that route would have prevented the majority from claiming that it means only to leave this issue to the democratic process—that it does not have a dog in the fight. See *ante*, at 38–39, 65. And indeed, doing so might have suggested a revolutionary proposition: that the fetus is itself a constitutionally protected "person," such that an abortion ban is constitutionally *mandated*. The majority therefore chooses the second path, arguing that the Fourteenth Amendment does

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According to the majority, no liberty interest is present because (and only because) the law offered no protection to the woman's choice in the 19th century. But here is the rub. The law also did not then (and would not for ages) protect a wealth of other things. It did not protect the rights recognized in Lawrence and Obergefell to same-sex intimacy and marriage. It did not protect the right recognized in *Loving* to marry across racial lines. It did not protect the right recognized in *Griswold* to contraceptive use. For that matter, it did not protect the right recognized in Skinner v. Oklahoma ex rel. Williamson, 316 U.S. 535 (1942), not to be sterilized without consent. So if the majority is right in its legal analysis, all those decisions were wrong, and all those matters properly belong to the States too—whatever the particular state interests involved. And if that is true, it is impossible to understand (as a matter of logic and principle) how the majority can say that its opinion today does not threaten-does not even "undermine"-any number of other constitutional rights. Ante, at 32.8

Nor does it even help just to take the majority at its word. Assume the majority is sincere in saying, for whatever reason, that it will go so far and no further. Scout's honor. Still, the future significance of today's opinion will be decided in the future. And law often has a way of evolving

not conceive of the abortion decision as implicating liberty, because the law in the 19th century gave that choice no protection. The trouble is that the chosen path—which is, again, the solitary rationale for the Court's decision—provides no way to distinguish between the right to choose an abortion and a range of other rights, including contraception.

⁸The majority briefly (very briefly) gestures at the idea that some *stare decisis* factors might play out differently with respect to these other constitutional rights. But the majority gives no hint as to why. And the majority's (mis)treatment of *stare decisis* in this case provides little reason to think that the doctrine would stand as a barrier to the majority's redoing any other decision it considered egregiously wrong. See *infra*, at 30–57.

without regard to original intentions—a way of actually following where logic leads, rather than tolerating hard-toexplain lines. Rights can expand in that way. Dissenting in Lawrence, Justice Scalia explained why he took no comfort in the Court's statement that a decision recognizing the right to same-sex intimacy did "not involve" same-sex marriage. 539 U.S., at 604. That could be true, he wrote, "only if one entertains the belief that principle and logic have nothing to do with the decisions of this Court." Id., at 605. Score one for the dissent, as a matter of prophecy. And logic and principle are not one-way ratchets. Rights can contract in the same way and for the same reason—because whatever today's majority might say, one thing really does lead to another. We fervently hope that does not happen because of today's decision. We hope that we will not join Justice Scalia in the book of prophets. But we cannot understand how anyone can be confident that today's opinion will be the last of its kind.

Consider, as our last word on this issue, contraception. The Constitution, of course, does not mention that word. And there is no historical right to contraception, of the kind the majority insists on. To the contrary, the American legal landscape in the decades after the Civil War was littered with bans on the sale of contraceptive devices. So again, there seem to be two choices. See *supra*, at 5, 26–27. If the majority is serious about its historical approach, then *Gris*wold and its progeny are in the line of fire too. Or if it is not serious, then . . . what is the basis of today's decision? If we had to guess, we suspect the prospects of this Court approving bans on contraception are low. But once again, the future significance of today's opinion will be decided in the future. At the least, today's opinion will fuel the fight to get contraception, and any other issues with a moral dimension, out of the Fourteenth Amendment and into state

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legislatures.9

Anyway, today's decision, taken on its own, is catastrophic enough. As a matter of constitutional method, the majority's commitment to replicate in 2022 every view about the meaning of liberty held in 1868 has precious little to recommend it. Our law in this constitutional sphere, as in most, has for decades upon decades proceeded differently. It has considered fundamental constitutional principles, the whole course of the Nation's history and traditions, and the step-by-step evolution of the Court's precedents. It is disciplined but not static. It relies on accumulated judgments, not just the sentiments of one long-ago generation of men (who themselves believed, and drafted the Constitution to reflect, that the world progresses). And by doing so, it includes those excluded from that olden conversation, rather than perpetuating its bounds.

As a matter of constitutional substance, the majority's opinion has all the flaws its method would suggest. Because laws in 1868 deprived women of any control over their bodies, the majority approves States doing so today. Because those laws prevented women from charting the course of their own lives, the majority says States can do the same again. Because in 1868, the government could tell a pregnant woman—even in the first days of her pregnancy—that she could do nothing but bear a child, it can once more impose that command. Today's decision strips women of agency over what even the majority agrees is a

⁹As this Court has considered this case, some state legislators have begun to call for restrictions on certain forms of contraception. See I. Stevenson, After *Roe* Decision, Idaho Lawmakers May Consider Restricting Some Contraception, Idaho Statesman (May 10, 2022), https://www.idahostatesman.com/news/politics-government/state-politics/article261207007.html; T. Weinberg, "Anything's on the Table": Missouri Legislature May Revisit Contraceptive Limits Post-*Roe*, Missouri Independent (May 20, 2022), https://www.missouriindependent.com/2022/05/20/anythings-on-the-table-missouri-legislature-may-revisit-contraceptive-limits-post-roe/.

contested and contestable moral issue. It forces her to carry out the State's will, whatever the circumstances and whatever the harm it will wreak on her and her family. In the Fourteenth Amendment's terms, it takes away her liberty. Even before we get to *stare decisis*, we dissent.

TT

By overruling *Roe*, *Casey*, and more than 20 cases reaffirming or applying the constitutional right to abortion, the majority abandons *stare decisis*, a principle central to the rule of law. "*Stare decisis*" means "to stand by things decided." Black's Law Dictionary 1696 (11th ed. 2019). Blackstone called it the "established rule to abide by former precedents." 1 Blackstone 69. *Stare decisis* "promotes the evenhanded, predictable, and consistent development of legal principles." *Payne*, 501 U. S., at 827. It maintains a stability that allows people to order their lives under the law. See H. Hart & A. Sacks, The Legal Process: Basic Problems in the Making and Application of Law 568–569 (1994).

Stare decisis also "contributes to the integrity of our constitutional system of government" by ensuring that decisions "are founded in the law rather than in the proclivities of individuals." Vasquez, 474 U.S., at 265. As Hamilton wrote: It "avoid[s] an arbitrary discretion in the courts." The Federalist No. 78, p. 529 (J. Cooke ed. 1961) (A. Hamilton). And as Blackstone said before him: It "keep[s] the scale of justice even and steady, and not liable to waver with every new judge's opinion." 1 Blackstone 69. The "glory" of our legal system is that it "gives preference to precedent rather than . . . jurists." H. Humble, Departure From Precedent, 19 Mich. L. Rev. 608, 614 (1921). That is why, the story goes, Chief Justice John Marshall donned a plain black robe when he swore the oath of office. That act personified an American tradition. Judges' personal preferences do not make law; rather, the law speaks through

them.

That means the Court may not overrule a decision, even a constitutional one, without a "special justification." *Gamble* v. *United States*, 587 U. S. ____, ___ (2019) (slip op., at 11). *Stare decisis* is, of course, not an "inexorable command"; it is sometimes appropriate to overrule an earlier decision. *Pearson* v. *Callahan*, 555 U. S. 223, 233 (2009). But the Court must have a good reason to do so over and above the belief "that the precedent was wrongly decided." *Halliburton Co.* v. *Erica P. John Fund, Inc.*, 573 U. S. 258, 266 (2014). "[I]t is not alone sufficient that we would decide a case differently now than we did then." *Kimble* v. *Marvel Entertainment, LLC*, 576 U. S. 446, 455 (2015).

The majority today lists some 30 of our cases as overruling precedent, and argues that they support overruling Roe and Casey. But none does, as further described below and in the Appendix. See *infra*, at 61–66. In some, the Court only partially modified or clarified a precedent. And in the rest, the Court relied on one or more of the traditional stare decisis factors in reaching its conclusion. The Court found, for example, (1) a change in legal doctrine that undermined or made obsolete the earlier decision; (2) a factual change that had the same effect; or (3) an absence of reliance because the earlier decision was less than a decade old. (The majority is wrong when it says that we insist on a test of changed law or fact alone, although that is present in most of the cases. See *ante*, at 69.) None of those factors apply here: Nothing—and in particular, no significant legal or factual change—supports overturning a half-century of settled law giving women control over their reproductive lives.

First, for all the reasons we have given, *Roe* and *Casey* were correct. In holding that a State could not "resolve" the debate about abortion "in such a definitive way that a woman lacks all choice in the matter," the Court protected women's liberty and women's equality in a way comporting with our Fourteenth Amendment precedents. *Casey*, 505

U. S., at 850. Contrary to the majority's view, the legal status of abortion in the 19th century does not weaken those decisions. And the majority's repeated refrain about "usurp[ing]" state legislatures' "power to address" a publicly contested question does not help it on the key issue here. *Ante*, at 44; see *ante*, at 1. To repeat: The point of a right is to shield individual actions and decisions "from the vicissitudes of political controversy, to place them beyond the reach of majorities and officials and to establish them as legal principles to be applied by the courts." *Barnette*, 319 U. S., at 638; *supra*, at 7. However divisive, a right is not at the people's mercy.

In any event "[w]hether or not we . . . agree" with a prior precedent is the beginning, not the end, of our analysis—and the remaining "principles of stare decisis weigh heavily against overruling" Roe and Casey. Dickerson v. United States, 530 U. S. 428, 443 (2000). Casey itself applied those principles, in one of this Court's most important precedents about precedent. After assessing the traditional stare decisis factors, Casey reached the only conclusion possible—that stare decisis operates powerfully here. It still does. The standards Roe and Casey set out are perfectly workable. No changes in either law or fact have eroded the two decisions. And tens of millions of American women have relied, and continue to rely, on the right to choose. So under traditional stare decisis principles, the majority has no special justification for the harm it causes.

And indeed, the majority comes close to conceding that point. The majority barely mentions any legal or factual changes that have occurred since *Roe* and *Casey*. It suggests that the two decisions are hard for courts to implement, but cannot prove its case. In the end, the majority says, all it must say to override *stare decisis* is one thing: that it believes *Roe* and *Casey* "egregiously wrong." *Ante*, at 70. That rule could equally spell the end of any precedent with which a bare majority of the present Court disagrees.

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So how does that approach prevent the "scale of justice" from "waver[ing] with every new judge's opinion"? 1 Blackstone 69. It does not. It makes radical change too easy and too fast, based on nothing more than the new views of new judges. The majority has overruled *Roe* and *Casey* for one and only one reason: because it has always despised them, and now it has the votes to discard them. The majority thereby substitutes a rule by judges for the rule of law.

Α

Contrary to the majority's view, there is nothing unworkable about *Casey*'s "undue burden" standard. Its primary focus on whether a State has placed a "substantial obstacle" on a woman seeking an abortion is "the sort of inquiry familiar to judges across a variety of contexts." *June Medical Services L. L. C.* v. *Russo*, 591 U. S. ____, ___ (2020) (slip op., at 6) (ROBERTS, C. J., concurring in judgment). And it has given rise to no more conflict in application than many standards this Court and others unhesitatingly apply every day.

General standards, like the undue burden standard, are ubiquitous in the law, and particularly in constitutional adjudication. When called on to give effect to the Constitution's broad principles, this Court often crafts flexible standards that can be applied case-by-case to a myriad of unforeseeable circumstances. See *Dickerson*, 530 U. S., at 441 ("No court laying down a general rule can possibly foresee the various circumstances" in which it must apply). So, for example, the Court asks about undue or substantial burdens on speech, on voting, and on interstate commerce. See, *e.g.*, *Arizona Free Enterprise Club's Freedom Club PAC* v. *Bennett*, 564 U. S. 721, 748 (2011); *Burdick* v. *Takushi*, 504 U. S. 428, 433–434 (1992); *Pike* v. *Bruce Church*, *Inc.*, 397 U. S. 137, 142 (1970). The *Casey* undue burden standard is the same. It also resembles general standards that courts

work with daily in other legal spheres—like the "rule of reason" in antitrust law or the "arbitrary and capricious" standard for agency decisionmaking. See *Standard Oil Co. of N. J. v. United States*, 221 U. S. 1, 62 (1911); *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U. S. 29, 42–43 (1983). Applying general standards to particular cases is, in many contexts, just what it means to do law.

And the undue burden standard has given rise to no unusual difficulties. Of course, it has provoked some disagreement among judges. Casey knew it would: That much "is to be expected in the application of any legal standard which must accommodate life's complexity." 505 U.S., at 878 (plurality opinion). Which is to say: That much is to be expected in the application of any legal standard. But the majority vastly overstates the divisions among judges applying the standard. We count essentially two. THE CHIEF JUSTICE disagreed with other Justices in the June Medical majority about whether Casey called for weighing the benefits of an abortion regulation against its burdens. See 591 U. S., at _____ (slip op., at 6-7); ante, at 59, 60, and n. 53.10 We agree that the *June Medical* difference is a difference—but not one that would actually make a difference in the result of most cases (it did not in *June Medical*), and not one incapable of resolution were it ever to matter. As for lower courts, there is now a one-year-old, one-to-one Circuit split about how the undue burden standard applies to state laws that ban abortions for certain reasons, like fetal abnormality. See *ante*, at 61, and n. 57. That is about it, as far as we can see. 11 And that is not much. This Court

¹⁰ Some lower courts then differed over which opinion in *June Medical* was controlling—but that is a dispute not about the undue burden standard, but about the "*Marks* rule," which tells courts how to determine the precedential effects of a divided decision.

¹¹The rest of the majority's supposed splits are, shall we say, unim-

mostly does not even grant certiorari on one-year-old, one-to-one Circuit splits, because we know that a bit of disagreement is an inevitable part of our legal system. To borrow an old saying that might apply here: Not one or even a couple of swallows can make the majority's summer.

Anyone concerned about workability should consider the majority's substitute standard. The majority says a law regulating or banning abortion "must be sustained if there is a rational basis on which the legislature could have thought that it would serve legitimate state interests." Ante, at 77. And the majority lists interests like "respect for and preservation of prenatal life," "protection of maternal health," elimination of certain "medical procedures," "mitigation of fetal pain," and others. Ante, at 78. This Court will surely face critical questions about how that test applies. Must a state law allow abortions when necessary to protect a woman's life and health? And if so, exactly when? How much risk to a woman's life can a State force

pressive. The majority says that lower courts have split over how to apply the undue burden standard to parental notification laws. See ante, at 60, and n. 54. But that is not so. The state law upheld had an exemption for minors demonstrating adequate maturity, whereas the ones struck down did not. Compare Planned Parenthood of Blue Ridge v. Camblos, 155 F. 3d 352, 383-384 (CA4 1998), with Planned Parenthood of Ind. & Ky., Inc. v. Adams, 937 F. 3d 973, 981 (CA7 2019), cert. granted, judgment vacated, 591 U.S. ___ (2020), and Planned Parenthood, Sioux Falls Clinic v. Miller, 63 F. 3d 1452, 1460 (CAS 1995). The majority says there is a split about bans on certain types of abortion procedures. See ante, at 61, and n. 55. But the one court to have separated itself on that issue did so based on a set of factual findings significantly different from those in other cases. Compare Whole Woman's Health v. Paxton, 10 F. 4th 430, 447-453 (CA5 2021), with EMW Women's Surgical Center, P.S.C. v. Friedlander, 960 F. 3d 785, 798–806 (CA6 2020), and West Ala. Women's Center v. Williamson, 900 F. 3d 1310, 1322–1324 (CA11 2018). Finally, the majority says there is a split about whether an increase in travel time to reach a clinic is an undue burden. See ante, at 61, and n. 56. But the cases to which the majority refers predate this Court's decision in Whole Woman's Health v. Hellerstedt, 579 U.S. 582 (2016), which clarified how to apply the undue burden standard to that context.

her to incur, before the Fourteenth Amendment's protection of life kicks in? Suppose a patient with pulmonary hypertension has a 30-to-50 percent risk of dying with ongoing pregnancy; is that enough? And short of death, how much illness or injury can the State require her to accept, consistent with the Amendment's protection of liberty and equality? Further, the Court may face questions about the application of abortion regulations to medical care most people view as quite different from abortion. What about the morning-after pill? IUDs? In vitro fertilization? And how about the use of dilation and evacuation or medication for miscarriage management? See generally L. Harris, Navigating Loss of Abortion Services—A Large Academic Medical Center Prepares for the Overturn of *Roe* v. *Wade*, 386 New England J. Med. 2061 (2022).¹²

Finally, the majority's ruling today invites a host of questions about interstate conflicts. See *supra*, at 3; see generally D. Cohen, G. Donley, & R. Rebouché, The New Abortion Battleground, 123 Colum. L. Rev. (forthcoming 2023), https://ssrn.com/abstract=4032931. Can a State bar women from traveling to another State to obtain an abortion? Can a State prohibit advertising out-of-state abortions or helping women get to out-of-state providers? Can a State inter-

¹²To take just the last, most medical treatments for miscarriage are identical to those used in abortions. See Kaiser Family Foundation (Kaiser), G. Weigel, L. Sobel, & A. Salganicoff, Understanding Pregnancy Loss in the Context of Abortion Restrictions and Fetal Harm Laws (Dec. 4, 2019), https://www.kff.org/womens-health-policy/issue-brief/understanding-pregnancy-loss-in-the-context-of-abortion-restrictions-and-fetal-harm-laws/. Blanket restrictions on "abortion" procedures and medications therefore may be understood to deprive women of effective treatment for miscarriages, which occur in about 10 to 30 percent of pregnancies. See Health Affairs, J. Strasser, C. Chen, S. Rosenbaum, E. Schenk, & E. Dewhurst, Penalizing Abortion Providers Will Have Ripple Effects Across Pregnancy Care (May 3, 2022), https://www.healthaffairs.org/do/10.1377/forefront.20220503.129912/.

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fere with the mailing of drugs used for medication abortions? The Constitution protects travel and speech and interstate commerce, so today's ruling will give rise to a host of new constitutional questions. Far from removing the Court from the abortion issue, the majority puts the Court at the center of the coming "interjurisdictional abortion wars." *Id.*, at ___ (draft, at 1).

In short, the majority does not save judges from unwieldy tests or extricate them from the sphere of controversy. To the contrary, it discards a known, workable, and predictable standard in favor of something novel and probably far more complicated. It forces the Court to wade further into hotly contested issues, including moral and philosophical ones, that the majority criticizes *Roe* and *Casey* for addressing.

В

When overruling constitutional precedent, the Court has almost always pointed to major legal or factual changes undermining a decision's original basis. A review of the Appendix to this dissent proves the point. See *infra*, at 61–66. Most "successful proponent[s] of overruling precedent," this Court once said, have carried "the heavy burden of persuading the Court that changes in society or in the law dictate that the values served by stare decisis yield in favor of a greater objective." Vasquez, 474 U.S., at 266. Certainly, that was so of the main examples the majority cites: Brown v. Board of Education, 347 U. S. 483 (1954), and West Coast Hotel Co. v. Parrish, 300 U. S. 379 (1937). But it is not so today. Although nodding to some arguments others have made about "modern developments," the majority does not really rely on them, no doubt seeing their slimness. Ante, at 33; see ante, at 34. The majority briefly invokes the current controversy over abortion. See ante, at 70–71. But it has to acknowledge that the same dispute has existed for

decades: Conflict over abortion is not a change but a constant. (And as we will later discuss, the presence of that continuing division provides more of a reason to stick with, than to jettison, existing precedent. See *infra*, at 55–57.) In the end, the majority throws longstanding precedent to the winds without showing that anything significant has changed to justify its radical reshaping of the law. See *ante*, at 43.

1

Subsequent legal developments have only reinforced Roe and Casey. The Court has continued to embrace all the decisions Roe and Casey cited, decisions which recognize a constitutional right for an individual to make her own choices about "intimate relationships, the family," and contraception. Casey, 505 U.S., at 857. Roe and Casey have themselves formed the legal foundation for subsequent decisions protecting these profoundly personal choices. As discussed earlier, the Court relied on Casey to hold that the Fourteenth Amendment protects same-sex intimate relationships. See Lawrence, 539 U.S., at 578; supra, at 23. The Court later invoked the same set of precedents to accord constitutional recognition to same-sex marriage. See Obergefell, 576 U. S., at 665–666; supra, at 23. In sum, Roe and Casey are inextricably interwoven with decades of precedent about the meaning of the Fourteenth Amendment. See *supra*, at 21–24. While the majority might wish it otherwise, Roe and Casey are the very opposite of "obsolete constitutional thinking." Agostini v. Felton, 521 U.S. 203, 236 (1997) (quoting Casey, 505 U.S., at 857).

Moreover, no subsequent factual developments have undermined *Roe* and *Casey*. Women continue to experience unplanned pregnancies and unexpected developments in pregnancies. Pregnancies continue to have enormous physical, social, and economic consequences. Even an uncompli-

cated pregnancy imposes significant strain on the body, unavoidably involving significant physiological change and excruciating pain. For some women, pregnancy and childbirth can mean life-altering physical ailments or even death. Today, as noted earlier, the risks of carrying a pregnancy to term dwarf those of having an abortion. See *supra*, at 22. Experts estimate that a ban on abortions increases maternal mortality by 21 percent, with white women facing a 13 percent increase in maternal mortality while black women face a 33 percent increase.¹³ Pregnancy and childbirth may also impose large-scale financial costs. The majority briefly refers to arguments about changes in laws relating to healthcare coverage, pregnancy discrimination, and family leave. See ante, at 33-34. Many women, however, still do not have adequate healthcare coverage before and after pregnancy; and, even when insurance coverage is available, healthcare services may be far away. 14 Women also continue to face pregnancy discrimination that interferes with their ability to earn a living. Paid family leave remains inaccessible to many who need it most. Only 20 percent of private-sector workers have access to paid family leave, including a mere 8 percent of workers in the bottom

¹³ See L. Harris, Navigating Loss of Abortion Services—A Large Academic Medical Center Prepares for the Overturn of *Roe* v. *Wade*, 386 New England J. Med. 2061, 2063 (2022). This projected racial disparity reflects existing differences in maternal mortality rates for black and white women. Black women are now three to four times more likely to die during or after childbirth than white women, often from preventable causes. See Brief for Howard University School of Law Human and Civil Rights Clinic as *Amicus Curiae* 18.

¹⁴See Centers for Medicare and Medicaid Services, Issue Brief: Improving Access to Maternal Health Care in Rural Communities 4, 8, 11 (Sept. 2019), https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/rural-health/09032019-Maternal-Health-Care-in-Rural-Communities.pdf. In Mississippi, for instance, 19 percent of women of reproductive age are uninsured and 60 percent of counties lack a single obstetrician-gynecologist. Brief for Lawyers' Committee for Civil Rights Under Law et al. as *Amici Curiae* 12–13.

quartile of wage earners.15

The majority briefly notes the growing prevalence of safe haven laws and demand for adoption, see *ante*, at 34, and nn. 45–46, but, to the degree that these are changes at all, they too are irrelevant. Neither reduces the health risks or financial costs of going through pregnancy and child-birth. Moreover, the choice to give up parental rights after giving birth is altogether different from the choice not to carry a pregnancy to term. The reality is that few women denied an abortion will choose adoption. The vast majority will continue, just as in *Roe* and *Casey*'s time, to shoulder the costs of childrearing. Whether or not they choose to parent, they will experience the profound loss of autonomy and dignity that coerced pregnancy and birth always impose. 18

¹⁵Dept. of Labor, National Compensation Survey: Employee Benefits in the United States, Table 31 (Sept. 2020), https://www.bls.gov/ncs/ebs/benefits/2020/employee-benefits-in-the-united-states-march-2020.pdf#page=299.

¹⁶ Safe haven laws, which allow parents to leave newborn babies in designated safe spaces without threat of prosecution, were not enacted as an alternative to abortion, but in response to rare situations in which birthing mothers in crisis would kill their newborns or leave them to die. See Centers for Disease Control and Prevention (CDC), R. Wilson, J. Klevens, D. Williams, & L. Xu, Infant Homicides Within the Context of Safe Haven Laws—United States, 2008–2017, 69 Morbidity and Mortality Weekly Report 1385 (2020).

¹⁷A study of women who sought an abortion but were denied one because of gestational limits found that only 9 percent put the child up for adoption, rather than parenting themselves. See G. Sisson, L. Ralph, H. Gould, & D. Foster, Adoption Decision Making Among Women Seeking Abortion, 27 Women's Health Issues 136, 139 (2017).

¹⁸The majority finally notes the claim that "people now have a new appreciation of fetal life," partly because of viewing sonogram images. *Ante*, at 34. It is hard to know how anyone would evaluate such a claim and as we have described above, the majority's reasoning does not rely on any reevaluation of the interest in protecting fetal life. See *supra*, at 26, and n. 7. It is worth noting that sonograms became widely used in

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Mississippi's own record illustrates how little facts on the ground have changed since *Roe* and *Casey*, notwithstanding the majority's supposed "modern developments." Ante, at 33. Sixty-two percent of pregnancies in Mississippi are unplanned, yet Mississippi does not require insurance to cover contraceptives and prohibits educators from demonstrating proper contraceptive use.¹⁹ The State neither bans pregnancy discrimination nor requires provision of paid parental leave. Brief for Yale Law School Information Society Project as Amicus Curiae 13 (Brief for Yale Law School); Brief for National Women's Law Center et al. as Amici Curiae 32. It has strict eligibility requirements for Medicaid and nutrition assistance, leaving many women and families without basic medical care or enough food. See Brief for 547 Deans, Chairs, Scholars and Public Health Professionals et al. as Amici Curiae 32-34 (Brief for 547 Deans). Although 86 percent of pregnancy-related deaths in the State are due to postpartum complications, Mississippi rejected federal funding to provide a year's worth of Medicaid coverage to women after giving birth. See Brief for Yale Law School 12–13. Perhaps unsurprisingly, health outcomes in Mississippi are abysmal for both women and children. Mississippi has the highest infant mortality rate in the country,

the 1970s, long before *Casey*. Today, 60 percent of women seeking abortions have at least one child, and one-third have two or more. See CDC, K. Kortsmit et al., Abortion Surveillance—United States, 2019, 70 Morbidity and Mortality Weekly Report 6 (2021). These women know, even as they choose to have an abortion, what it is to look at a sonogram image and to value a fetal life.

¹⁹ Guttmacher Institute, K. Kost, Unintended Pregnancy Rates at the State Level: Estimates for 2010 and Trends Since 2002, Table 1 (2015), https://www.guttmacher.org/sites/default/files/report_pdf/stateup10.pdf; Kaiser, State Requirements for Insurance Coverage of Contraceptives (May 1, 2022), https://www.kff.org/state-category/womens-health/family-planning; Miss. Code Ann. §37–13–171(2)(d) (Cum. Supp. 2021) ("In no case shall the instruction or program include any demonstration of how condoms or other contraceptives are applied").

and some of the highest rates for preterm birth, low birth-weight, cesarean section, and maternal death.²⁰ It is approximately 75 times more dangerous for a woman in the State to carry a pregnancy to term than to have an abortion. See Brief for 547 Deans 9–10. We do not say that every State is Mississippi, and we are sure some have made gains since *Roe* and *Casey* in providing support for women and children. But a state-by-state analysis by public health professionals shows that States with the most restrictive abortion policies also continue to invest the least in women's and children's health. See Brief for 547 Deans 23–34.

The only notable change we can see since *Roe* and *Casey* cuts in favor of adhering to precedent: It is that American abortion law has become more and more aligned with other nations. The majority, like the Mississippi Legislature, claims that the United States is an extreme outlier when it comes to abortion regulation. See *ante*, at 6, and n. 15. The global trend, however, has been toward increased provision of legal and safe abortion care. A number of countries, including New Zealand, the Netherlands, and Iceland, permit abortions up to a roughly similar time as *Roe* and *Casey* set. See Brief for International and Comparative Legal Scholars as *Amici Curiae* 18–22. Canada has decriminalized abortion at any point in a pregnancy. See *id.*, at 13–15. Most Western European countries impose restrictions on abor-

²⁰See CDC, Infant Mortality Rates by State (Mar. 3, 2022), https://www.cdc.gov/nchs/pressroom/sosmap/infant_mortality_rates/infant_mortality.htm; Mississippi State Dept. of Health, Infant Mortality Report 2019 & 2020, pp. 18–19 (2021), https://www.msdh.ms.gov/msdhsite/_static/resources/18752.pdf; CDC, Percentage of Babies Born Low Birthweight by State (Feb. 25, 2022), https://www.cdc.gov/nchs/pressroom/sosmap/lbw_births/lbw.htm; CDC, Cesarean Delivery Rate by State (Feb. 25, 2022), https://www.cdc.gov/nchs/pressroom/sosmap/cesarean_births/cesareans.htm; Mississippi State Dept. of Health, Mississippi Maternal Mortality Report 2013–2016, pp. 5, 25 (Mar. 2021), https://www.msdh.ms.gov/msdhsite/_static/resources/8127.pdf.

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tion after 12 to 14 weeks, but they often have liberal exceptions to those time limits, including to prevent harm to a woman's physical or mental health. See *id.*, at 24–27; Brief for European Law Professors as *Amici Curiae* 16–17, Appendix. They also typically make access to early abortion easier, for example, by helping cover its cost.²¹ Perhaps most notable, more than 50 countries around the world—in Asia, Latin America, Africa, and Europe—have expanded access to abortion in the past 25 years. See Brief for International and Comparative Legal Scholars as *Amici Curiae* 28–29. In light of that worldwide liberalization of abortion laws, it is American States that will become international outliers after today.

In sum, the majority can point to neither legal nor factual developments in support of its decision. Nothing that has happened in this country or the world in recent decades undermines the core insight of *Roe* and *Casey*. It continues to be true that, within the constraints those decisions established, a woman, not the government, should choose whether she will bear the burdens of pregnancy, childbirth, and parenting.

2

In support of its holding, see *ante*, at 40, the majority invokes two watershed cases overruling prior constitutional precedents: *West Coast Hotel Co.* v. *Parrish* and *Brown* v. *Board of Education*. But those decisions, unlike today's, responded to changed law and to changed facts and attitudes that had taken hold throughout society. As *Casey* recognized, the two cases are relevant only to show—by stark contrast—how unjustified overturning the right to choose is. See 505 U. S., at 861–864.

West Coast Hotel overruled Adkins v. Children's Hospital

²¹ See D. Grossman, K. Grindlay, & B. Burns, Public Funding for Abortion Where Broadly Legal, 94 Contraception 451, 458 (2016) (discussing funding of abortion in European countries).

of D. C., 261 U. S. 525 (1923), and a whole line of cases beginning with Lochner v. New York, 198 U. S. 45 (1905). Adkins had found a state minimum-wage law unconstitutional because, in the Court's view, the law interfered with a constitutional right to contract. 261 U.S., at 554-555. But then the Great Depression hit, bringing with it unparalleled economic despair. The experience undermined—in fact, it disproved—Adkins's assumption that a wholly unregulated market could meet basic human needs. As Justice Jackson (before becoming a Justice) wrote of that time: "The older world of *laissez faire* was recognized everywhere outside the Court to be dead." The Struggle for Judicial Supremacy 85 (1941). In West Coast Hotel, the Court caught up, recognizing through the lens of experience the flaws of existing legal doctrine. See also ante, at 11 (ROBERTS, C. J., concurring in judgment). The havor the Depression had worked on ordinary Americans, the Court noted, was "common knowledge through the length and breadth of the land." 300 U. S., at 399. The *laissez-faire* approach had led to "the exploiting of workers at wages so low as to be insufficient to meet the bare cost of living." *Ibid*. And since Adkins was decided, the law had also changed. In several decisions, the Court had started to recognize the power of States to implement economic policies designed to enhance their citizens' economic well-being. See, e.g., Nebbia v. New York, 291 U.S. 502 (1934); O'Gorman & Young, Inc. v. Hartford Fire Ins. Co., 282 U.S. 251 (1931). The statements in those decisions, West Coast Hotel explained, were "impossible to reconcile" with Adkins. 300 U.S., at 398. There was no escaping the need for *Adkins* to go.

Brown v. Board of Education overruled Plessy v. Ferguson, 163 U. S. 537 (1896), along with its doctrine of "separate but equal." By 1954, decades of Jim Crow had made clear what Plessy's turn of phrase actually meant: "inherent[] [in]equal[ity]." Brown, 347 U. S., at 495. Segregation

was not, and could not ever be, consistent with the Reconstruction Amendments, ratified to give the former slaves full citizenship. Whatever might have been thought in *Plessy's* time, the *Brown* Court explained, both experience and "modern authority" showed the "detrimental effect[s]" of state-sanctioned segregation: It "affect[ed] [children's] hearts and minds in a way unlikely ever to be undone." 347 U. S., at 494. By that point, too, the law had begun to reflect that understanding. In a series of decisions, the Court had held unconstitutional public graduate schools' exclusion of black students. See, e.g., Sweatt v. Painter, 339 U. S. 629 (1950); Sipuel v. Board of Regents of Univ. of Okla., 332 U. S. 631 (1948) (per curiam); Missouri ex rel. Gaines v. Canada, 305 U.S. 337 (1938). The logic of those cases, *Brown* held, "appl[ied] with added force to children in grade and high schools." 347 U.S., at 494. Changed facts and changed law required *Plessy*'s end.

The majority says that in recognizing those changes, we are implicitly supporting the half-century interlude between *Plessy* and *Brown*. See *ante*, at 70. That is not so. First, if the *Brown* Court had used the majority's method of constitutional construction, it might not ever have overruled *Plessy*, whether 5 or 50 or 500 years later. *Brown* thought that whether the ratification-era history supported desegregation was "[a]t best . . . inconclusive." 347 U.S., at 489. But even setting that aside, we are not saying that a decision can *never* be overruled just because it is terribly wrong. Take West Virginia Bd. of Ed. v. Barnette, 319 U. S. 624, which the majority also relies on. See ante, at 40–41, 70. That overruling took place just three years after the initial decision, before any notable reliance interests had developed. It happened as well because individual Justices changed their minds, not because a new majority wanted to undo the decisions of their predecessors. Both *Barnette* and *Brown*, moreover, share another feature setting them apart from the Court's ruling today. They protected individual

rights with a strong basis in the Constitution's most fundamental commitments; they did not, as the majority does here, take away a right that individuals have held, and relied on, for 50 years. To take *that* action based on a new and bare majority's declaration that two Courts got the result egregiously wrong? And to justify that action by reference to *Barnette*? Or to *Brown*—a case in which the Chief Justice also wrote an (11-page) opinion in which the entire Court could speak with one voice? These questions answer themselves.

Casey itself addressed both West Coast Hotel and Brown, and found that neither supported Roe's overruling. In West Coast Hotel, Casey explained, "the facts of economic life" had proved "different from those previously assumed." 505 U. S., at 862. And even though "Plessy was wrong the day it was decided," the passage of time had made that ever more clear to ever more citizens: "Society's understanding of the facts" in 1954 was "fundamentally different" than in 1896. Id., at 863. So the Court needed to reverse course. "In constitutional adjudication as elsewhere in life, changed circumstances may impose new obligations." Id., at 864. And because such dramatic change had occurred, the public could understand why the Court was acting. "[T]he Nation could accept each decision" as a "response to the Court's constitutional duty." *Ibid*. But that would not be true of a reversal of Roe—"[b]ecause neither the factual underpinnings of Roe's central holding nor our understanding of it has changed." 505 U.S., at 864.

That is just as much so today, because *Roe* and *Casey* continue to reflect, not diverge from, broad trends in American society. It is, of course, true that many Americans, including many women, opposed those decisions when issued and do so now as well. Yet the fact remains: *Roe* and *Casey* were the product of a profound and ongoing change in women's roles in the latter part of the 20th century. Only a dozen years before *Roe*, the Court described women as "the center"

of home and family life," with "special responsibilities" that precluded their full legal status under the Constitution. Hoyt v. Florida, 368 U. S. 57, 62 (1961). By 1973, when the Court decided Roe, fundamental social change was underway regarding the place of women—and the law had begun to follow. See *Reed* v. *Reed*, 404 U. S. 71, 76 (1971) (recognizing that the Equal Protection Clause prohibits sex-based discrimination). By 1992, when the Court decided Casey, the traditional view of a woman's role as only a wife and mother was "no longer consistent with our understanding of the family, the individual, or the Constitution." 505 U. S., at 897; see *supra*, at 15, 23–24. Under that charter, Casey understood, women must take their place as full and equal citizens. And for that to happen, women must have control over their reproductive decisions. Nothing since Casey—no changed law, no changed fact—has undermined that promise.

C

The reasons for retaining Roe and Casey gain further strength from the overwhelming reliance interests those decisions have created. The Court adheres to precedent not just for institutional reasons, but because it recognizes that stability in the law is "an essential thread in the mantle of protection that the law affords the individual." Florida Dept. of Health and Rehabilitative Servs. v. Florida Nursing Home Assn., 450 U.S. 147, 154 (1981) (Stevens, J., concurring). So when overruling precedent "would dislodge [individuals' settled rights and expectations, stare decisis has "added force." Hilton v. South Carolina Public Railways Comm'n, 502 U. S. 197, 202 (1991). Casey understood that to deny individuals' reliance on Roe was to "refuse to face the fact[s]." 505 U.S., at 856. Today the majority refuses to face the facts. "The most striking feature of the [majority] is the absence of any serious discussion" of how

its ruling will affect women. *Ante*, at 37. By characterizing *Casey*'s reliance arguments as "generalized assertions about the national psyche," *ante*, at 64, it reveals how little it knows or cares about women's lives or about the suffering its decision will cause.

In *Casey*, the Court observed that for two decades individuals "have organized intimate relationships and made" significant life choices "in reliance on the availability of abortion in the event that contraception should fail." 505 U. S., at 856. Over another 30 years, that reliance has solidified. For half a century now, in *Casey*'s words, "[t]he ability of women to participate equally in the economic and social life of the Nation has been facilitated by their ability to control their reproductive lives." *Ibid.*; see *supra*, at 23–24. Indeed, all women now of childbearing age have grown up expecting that they would be able to avail themselves of *Roe*'s and *Casey*'s protections.

The disruption of overturning *Roe* and *Casey* will therefore be profound. Abortion is a common medical procedure and a familiar experience in women's lives. About 18 percent of pregnancies in this country end in abortion, and about one quarter of American women will have an abortion before the age of 45.²² Those numbers reflect the predictable and life-changing effects of carrying a pregnancy, giving birth, and becoming a parent. As *Casey* understood, people today rely on their ability to control and time pregnancies when making countless life decisions: where to live, whether and how to invest in education or careers, how to allocate financial resources, and how to approach intimate and family relationships. Women may count on abortion access for when contraception fails. They may count on abortion access for when contraception cannot be used, for

²² See CDC, K. Kortsmit et al., Abortion Surveillance—United States, 2019, 70 Morbidity and Mortality Weekly Report 7 (2021); Brief for American College of Obstetricians and Gynecologists et al. as *Amici Curiae* 9.

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example, if they were raped. They may count on abortion for when something changes in the midst of a pregnancy, whether it involves family or financial circumstances, unanticipated medical complications, or heartbreaking fetal diagnoses. Taking away the right to abortion, as the majority does today, destroys all those individual plans and expectations. In so doing, it diminishes women's opportunities to participate fully and equally in the Nation's political, social, and economic life. See Brief for Economists as *Amici Curiae* 13 (showing that abortion availability has "large effects on women's education, labor force participation, occupations, and earnings" (footnotes omitted)).

The majority's response to these obvious points exists far from the reality American women actually live. The majority proclaims that "reproductive planning could take virtually immediate account of any sudden restoration of state authority to ban abortions." *Ante*, at 64 (quoting *Casey*, 505 U. S., at 856). The facts are: 45 percent of pregnancies in the United States are unplanned. See Brief for 547 Deans 5. Even the most effective contraceptives fail, and effective contraceptives are not universally accessible. And all sexual activity is consensual and not all contraceptive choices are made by the party who risks pregnancy. See Brief for Legal Voice et al. as *Amici Curiae* 18–19. The Mississippi law at issue here, for example, has no exception for rape or incest, even for underage women. Finally, the

²³Astoundingly, the majority casts this statement as a "conce[ssion]" from *Casey* with which it "agree[s]." *Ante*, at 64. In fact, *Casey* used this language as part of describing an argument that it *rejected*. See 505 U. S., at 856. It is only today's Court that endorses this profoundly mistaken view.

²⁴See Brief for 547 Deans 6–7 (noting that 51 percent of women who terminated their pregnancies reported using contraceptives during the month in which they conceived); Brief for Lawyers' Committee for Civil Rights Under Law et al. as *Amici Curiae* 12–14 (explaining financial and geographic barriers to access to effective contraceptives).

majority ignores, as explained above, that some women decide to have an abortion because their circumstances change during a pregnancy. See *supra*, at 49. Human bodies care little for hopes and plans. Events can occur after conception, from unexpected medical risks to changes in family circumstances, which profoundly alter what it means to carry a pregnancy to term. In all these situations, women have expected that they will get to decide, perhaps in consultation with their families or doctors but free from state interference, whether to continue a pregnancy. For those who will now have to undergo that pregnancy, the loss of *Roe* and *Casey* could be disastrous.

That is especially so for women without money. When we "count[] the cost of [Roe's] repudiation" on women who once relied on that decision, it is not hard to see where the greatest burden will fall. Casey, 505 U. S., at 855. In States that bar abortion, women of means will still be able to travel to obtain the services they need.²⁵ It is women who cannot afford to do so who will suffer most. These are the women most likely to seek abortion care in the first place. Women living below the federal poverty line experience unintended pregnancies at rates five times higher than higher income women do, and nearly half of women who seek abortion care live in households below the poverty line. See Brief for 547 Deans 7; Brief for Abortion Funds and Practical Support Organizations as Amici Curiae 8 (Brief for Abortion Funds).

²⁵This statement of course assumes that States are not successful in preventing interstate travel to obtain an abortion. See *supra*, at 3, 36–37. Even assuming that is so, increased out-of-state demand will lead to longer wait times and decreased availability of service in States still providing abortions. See Brief for State of California et al. as *Amici Curiae* 25–27. This is what happened in Oklahoma, Kansas, Colorado, New Mexico, and Nevada last fall after Texas effectively banned abortions past six weeks of gestation. See *United States* v. *Texas*, 595 U. S. ____, ___ (2021) (SOTOMAYOR, J., concurring in part and dissenting in part) (slip op., at 6).

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Even with *Roe*'s protection, these women face immense obstacles to raising the money needed to obtain abortion care early in their pregnancy. See Brief for Abortion Funds 7–12.²⁶ After today, in States where legal abortions are not available, they will lose any ability to obtain safe, legal abortion care. They will not have the money to make the trip necessary; or to obtain childcare for that time; or to take time off work. Many will endure the costs and risks of pregnancy and giving birth against their wishes. Others will turn in desperation to illegal and unsafe abortions. They may lose not just their freedom, but their lives.²⁷

Finally, the expectation of reproductive control is integral to many women's identity and their place in the Nation. See *Casey*, 505 U. S., at 856. That expectation helps define

²⁶The average cost of a first-trimester abortion is about \$500. See Brief for Abortion Funds 7. Federal insurance generally does not cover the cost of abortion, and 35 percent of American adults do not have cash on hand to cover an unexpected expense that high. Guttmacher Institute, M. Donovan, In Real Life: Federal Restrictions on Abortion Coverage and the Women They Impact (Jan. 5, 2017), https://www.guttmacher.org/gpr/2017/01/real-life-federal-restrictions-abortion-coverage-and-women-they-impact#:~:text=Although%20the%20Hyde%20Amendment% 20bars,provide%20abortion%20coverage%20to%20enrollees; Brief for Abortion Funds 11.

²⁷Mississippi is likely to be one of the States where these costs are highest, though history shows that it will have company. As described above, Mississippi provides only the barest financial support to pregnant women. See *supra*, at 41–42. The State will greatly restrict abortion care without addressing any of the financial, health, and family needs that motivate many women to seek it. The effects will be felt most severely, as they always have been, on the bodies of the poor. The history of state abortion restrictions is a history of heavy costs exacted from the most vulnerable women. It is a history of women seeking illegal abortions in hotel rooms and home kitchens; of women trying to self-induce abortions by douching with bleach, injecting lye, and penetrating themselves with knitting needles, scissors, and coat hangers. See L. Reagan, When Abortion Was a Crime 42–43, 198–199, 208–209 (1997). It is a history of women dying.

a woman as an "equal citizen[]," with all the rights, privileges, and obligations that status entails. *Gonzales*, 550 U. S., at 172 (Ginsburg, J., dissenting); see *supra*, at 23–24. It reflects that she is an autonomous person, and that society and the law recognize her as such. Like many constitutional rights, the right to choose situates a woman in relationship to others and to the government. It helps define a sphere of freedom, in which a person has the capacity to make choices free of government control. As *Casey* recognized, the right "order[s]" her "thinking" as well as her "living." 505 U. S., at 856. Beyond any individual choice about residence, or education, or career, her whole life reflects the control and authority that the right grants.

Withdrawing a woman's right to choose whether to continue a pregnancy does not mean that no choice is being made. It means that a majority of today's Court has wrenched this choice from women and given it to the States. To allow a State to exert control over one of "the most intimate and personal choices" a woman may make is not only to affect the course of her life, monumental as those effects might be. *Id.*, at 851. It is to alter her "views of [herself]" and her understanding of her "place[] in society" as someone with the recognized dignity and authority to make these choices. *Id.*, at 856. Women have relied on *Roe* and *Casey* in this way for 50 years. Many have never known anything else. When *Roe* and *Casey* disappear, the loss of power, control, and dignity will be immense.

The Court's failure to perceive the whole swath of expectations *Roe* and *Casey* created reflects an impoverished view of reliance. According to the majority, a reliance interest must be "very concrete," like those involving "property" or "contract." *Ante*, at 64. While many of this Court's cases addressing reliance have been in the "commercial context," *Casey*, 505 U. S., at 855, none holds that interests must be analogous to commercial ones to warrant *stare de-*

cisis protection.²⁸ This unprecedented assertion is, at bottom, a radical claim to power. By disclaiming any need to consider broad swaths of individuals' interests, the Court arrogates to itself the authority to overrule established legal principles without even acknowledging the costs of its decisions for the individuals who live under the law, costs that this Court's stare decisis doctrine instructs us to privilege when deciding whether to change course.

The majority claims that the reliance interests women have in *Roe* and *Casey* are too "intangible" for the Court to consider, even if it were inclined to do so. Ante, at 65. This is to ignore as judges what we know as men and women. The interests women have in *Roe* and *Casey* are perfectly, viscerally concrete. Countless women will now make different decisions about careers, education, relationships, and whether to try to become pregnant than they would have when *Roe* served as a backstop. Other women will carry pregnancies to term, with all the costs and risk of harm that involves, when they would previously have chosen to obtain an abortion. For millions of women, Roe and Casey have been critical in giving them control of their bodies and their lives. Closing our eyes to the suffering today's decision will impose will not make that suffering disappear. The majority cannot escape its obligation to "count[] the cost[s]" of its decision by invoking the "conflicting arguments" of "contending sides." Casey, 505 U.S., at 855; ante, at 65. Stare decisis requires that the Court calculate the costs of a decision's repudiation on those who have relied on the decision,

²⁸The majority's sole citation for its "concreteness" requirement is *Payne* v. *Tennessee*, 501 U. S. 808 (1991). But *Payne* merely discounted reliance interests in cases involving "procedural and evidentiary rules." *Id.*, at 828. Unlike the individual right at stake here, those rules do "not alter primary conduct." *Hohn* v. *United States*, 524 U. S. 236, 252 (1998). Accordingly, they generally "do not implicate the reliance interests of private parties" at all. *Alleyne* v. *United States*, 570 U. S. 99, 119 (2013) (SOTOMAYOR, J., concurring).

not on those who have disavowed it. See *Casey*, 505 U. S., at 855.

More broadly, the majority's approach to reliance cannot be reconciled with our Nation's understanding of constitutional rights. The majority's insistence on a "concrete," economic showing would preclude a finding of reliance on a wide variety of decisions recognizing constitutional rights such as the right to express opinions, or choose whom to marry, or decide how to educate children. The Court, on the majority's logic, could transfer those choices to the State without having to consider a person's settled understanding that the law makes them hers. That must be wrong. All those rights, like the right to obtain an abortion, profoundly affect and, indeed, anchor individual lives. To recognize that people have relied on these rights is not to dabble in abstractions, but to acknowledge some of the most "concrete" and familiar aspects of human life and liberty. Ante, at 64.

All those rights, like the one here, also have a societal dimension, because of the role constitutional liberties play in our structure of government. See, e.g., Dickerson, 530 U.S., at 443 (recognizing that *Miranda* "warnings have become part of our national culture" in declining to overrule Miranda v. Arizona, 384 U. S. 436 (1966)). Rescinding an individual right in its entirety and conferring it on the State, an action the Court takes today for the first time in history, affects all who have relied on our constitutional system of government and its structure of individual liberties protected from state oversight. Roe and Casey have of course aroused controversy and provoked disagreement. But the right those decisions conferred and reaffirmed is part of society's understanding of constitutional law and of how the Court has defined the liberty and equality that women are entitled to claim.

After today, young women will come of age with fewer

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rights than their mothers and grandmothers had. The majority accomplishes that result without so much as considering how women have relied on the right to choose or what it means to take that right away. The majority's refusal even to consider the life-altering consequences of reversing *Roe* and *Casey* is a stunning indictment of its decision.

Г

One last consideration counsels against the majority's ruling: the very controversy surrounding Roe and Casey. The majority accuses *Casey* of acting outside the bounds of the law to quell the conflict over abortion—of imposing an unprincipled "settlement" of the issue in an effort to end "national division." *Ante*, at 67. But that is not what *Casey* did. As shown above, Casey applied traditional principles of stare decisis—which the majority today ignores—in reaffirming Roe. Casey carefully assessed changed circumstances (none) and reliance interests (profound). It considered every aspect of how Roe's framework operated. It adhered to the law in its analysis, and it reached the conclusion that the law required. True enough that Casey took notice of the "national controversy" about abortion: The Court knew in 1992, as it did in 1973, that abortion was a "divisive issue." Casey, 505 U.S., at 867–868; see Roe, 410 U. S., at 116. But *Casey's* reason for acknowledging public conflict was the exact opposite of what the majority insinuates. Casey addressed the national controversy in order to emphasize how important it was, in that case of all cases, for the Court to stick to the law. Would that today's majority had done likewise.

Consider how the majority itself summarizes this aspect of *Casey*:

"The American people's belief in the rule of law would be shaken if they lost respect for this Court as an institution that decides important cases based on principle, not 'social and political pressures.' There is a special danger that the public will perceive a decision as having been made for unprincipled reasons when the Court overrules a controversial 'watershed' decision, such as *Roe*. A decision overruling *Roe* would be perceived as having been made 'under fire' and as a 'surrender to political pressure.'" *Ante*, at 66–67 (citations omitted).

That seems to us a good description. And it seems to us right. The majority responds (if we understand it correctly): well, yes, but we have to apply the law. See ante, at 67. To which Casey would have said: That is exactly the point. Here, more than anywhere, the Court needs to apply the law—particularly the law of stare decisis. Here, we know that citizens will continue to contest the Court's decision, because "[m]en and women of good conscience" deeply disagree about abortion. Casey, 505 U. S., at 850. When that contestation takes place—but when there is no legal basis for reversing course—the Court needs to be steadfast, to stand its ground. That is what the rule of law requires. And that is what respect for this Court depends on.

"The promise of constancy, once given" in so charged an environment, *Casey* explained, "binds its maker for as long as" the "understanding of the issue has not changed so fundamentally as to render the commitment obsolete." *Id.*, at 868. A breach of that promise is "nothing less than a breach of faith." *Ibid.* "[A]nd no Court that broke its faith with the people could sensibly expect credit for principle." *Ibid.* No Court breaking its faith in that way would *deserve* credit for principle. As one of *Casey*'s authors wrote in another case, "Our legitimacy requires, above all, that we adhere to *stare decisis*" in "sensitive political contexts" where "partisan controversy abounds." *Bush* v. *Vera*, 517 U. S. 952, 985 (1996) (opinion of O'Connor, J.).

Justice Jackson once called a decision he dissented from a "loaded weapon," ready to hand for improper uses. *Korematsu* v. *United States*, 323 U. S. 214, 246 (1944). We fear

BREYER, SOTOMAYOR, and KAGAN, JJ., dissenting

that today's decision, departing from *stare decisis* for no legitimate reason, is its own loaded weapon. Weakening *stare decisis* threatens to upend bedrock legal doctrines, far beyond any single decision. Weakening *stare decisis* creates profound legal instability. And as *Casey* recognized, weakening *stare decisis* in a hotly contested case like this one calls into question this Court's commitment to legal principle. It makes the Court appear not restrained but aggressive, not modest but grasping. In all those ways, today's decision takes aim, we fear, at the rule of law.

III

"Power, not reason, is the new currency of this Court's decisionmaking." Payne, 501 U.S., at 844 (Marshall, J., dissenting). Roe has stood for fifty years. Casey, a precedent about precedent specifically confirming Roe, has stood for thirty. And the doctrine of stare decisis—a critical element of the rule of law—stands foursquare behind their continued existence. The right those decisions established and preserved is embedded in our constitutional law, both originating in and leading to other rights protecting bodily integrity, personal autonomy, and family relationships. The abortion right is also embedded in the lives of women shaping their expectations, influencing their choices about relationships and work, supporting (as all reproductive rights do) their social and economic equality. Since the right's recognition (and affirmation), nothing has changed to support what the majority does today. Neither law nor facts nor attitudes have provided any new reasons to reach a different result than Roe and Casey did. All that has changed is this Court.

Mississippi—and other States too—knew exactly what they were doing in ginning up new legal challenges to *Roe* and *Casey*. The 15-week ban at issue here was enacted in 2018. Other States quickly followed: Between 2019 and 2021, eight States banned abortion procedures after six to

eight weeks of pregnancy, and three States enacted all-out bans.²⁹ Mississippi itself decided in 2019 that it had not gone far enough: The year after enacting the law under review, the State passed a 6-week restriction. A state senator who championed both Mississippi laws said the obvious out loud. "[A] lot of people thought," he explained, that "finally, we have" a conservative Court "and so now would be a good time to start testing the limits of Roe."30 In its petition for certiorari, the State had exercised a smidgen of restraint. It had urged the Court merely to roll back *Roe* and *Casey*, specifically assuring the Court that "the questions presented in this petition do not require the Court to overturn" those precedents. Pet. for Cert. 5; see ante, at 5-6 (ROBERTS, C. J., concurring in judgment). But as Mississippi grew ever more confident in its prospects, it resolved to go all in. It urged the Court to overrule *Roe* and *Casey*. Nothing but everything would be enough.

Earlier this Term, this Court signaled that Mississippi's stratagem would succeed. Texas was one of the fistful of States to have recently banned abortions after six weeks of pregnancy. It added to that "flagrantly unconstitutional" restriction an unprecedented scheme to "evade judicial"

²⁹Guttmacher Institute, E. Nash, State Policy Trends 2021: The Worst Year for Abortion Rights in Almost Half a Century (Dec. 16, 2021), https://www.guttmacher.org/article/2021/12/state-policy-trends-2021-worst-year-abortion-rights-almost-half-century; Guttmacher Institute, E. Nash, L. Mohammed, O. Cappello, & S. Naide, State Policy Trends 2020: Reproductive Health and Rights in a Year Like No Other (Dec. 15, 2020), https://www.guttmacher.org/article/2020/12/state-policy-trends-2020-reproductive-health-and-rights-year-no-other; Guttmacher Institute, E. Nash, L. Mohammed, O. Cappello, & S. Naide, State Policy Trends 2019: A Wave of Abortion Bans, But Some States Are Fighting Back (Dec. 10, 2019), https://www.guttmacher.org/article/2019/12/state-policy-trends-2019-wave-abortion-bans-some-states-are-fighting-back.

³⁰A. Pittman, Mississippi's Six-Week Abortion Ban at 5th Circuit Appeals Court Today, Jackson Free Press (Oct. 7, 2019), https://www.jacksonfreepress.com/news/2019/oct/07/mississippis-six-week-abortion-ban-5th-circuit-app/.

scrutiny." Whole Woman's Health v. Jackson, 594 U. S. ___, ___ (2021) (SOTOMAYOR, J., dissenting) (slip op., at 1). And five Justices acceded to that cynical maneuver. They let Texas defy this Court's constitutional rulings, nullifying Roe and Casey ahead of schedule in the Nation's second largest State.

And now the other shoe drops, courtesy of that same fiveperson majority. (We believe that THE CHIEF JUSTICE's opinion is wrong too, but no one should think that there is not a large difference between upholding a 15-week ban on the grounds he does and allowing States to prohibit abortion from the time of conception.) Now a new and bare majority of this Court—acting at practically the first moment possible—overrules *Roe* and *Casey*. It converts a series of dissenting opinions expressing antipathy toward Roe and Casev into a decision greenlighting even total abortion bans. See ante, at 57, 59, 63, and nn. 61–64 (relying on former dissents). It eliminates a 50-year-old constitutional right that safeguards women's freedom and equal station. It breaches a core rule-of-law principle, designed to promote constancy in the law. In doing all of that, it places in jeopardy other rights, from contraception to same-sex intimacy and marriage. And finally, it undermines the Court's legitimacy.

Casey itself made the last point in explaining why it would not overrule Roe—though some members of its majority might not have joined Roe in the first instance. Just as we did here, Casey explained the importance of stare decisis; the inappositeness of West Coast Hotel and Brown; the absence of any "changed circumstances" (or other reason) justifying the reversal of precedent. 505 U. S., at 864; see supra, at 30–33, 37–47. "[T]he Court," Casey explained, "could not pretend" that overruling Roe had any "justification beyond a present doctrinal disposition to come out differently from the Court of 1973." 505 U. S., at 864. And to overrule for that reason? Quoting Justice Stewart, Casey

explained that to do so—to reverse prior law "upon a ground no firmer than a change in [the Court's] membership"—would invite the view that "this institution is little different from the two political branches of the Government." *Ibid.* No view, *Casey* thought, could do "more lasting injury to this Court and to the system of law which it is our abiding mission to serve." *Ibid.* For overruling *Roe*, *Casey* concluded, the Court would pay a "terrible price." 505 U. S., at 864.

The Justices who wrote those words—O'Connor, Kennedy, and Souter—they were judges of wisdom. They would not have won any contests for the kind of ideological purity some court watchers want Justices to deliver. But if there were awards for Justices who left this Court better than they found it? And who for that reason left this country better? And the rule of law stronger? Sign those Justices up.

They knew that "the legitimacy of the Court [is] earned over time." Id., at 868. They also would have recognized that it can be destroyed much more quickly. They worked hard to avert that outcome in *Casey*. The American public, they thought, should never conclude that its constitutional protections hung by a thread—that a new majority, adhering to a new "doctrinal school," could "by dint of numbers" alone expunge their rights. *Id.*, at 864. It is hard—no, it is impossible—to conclude that anything else has happened here. One of us once said that "[i]t is not often in the law that so few have so quickly changed so much." S. Breyer, Breaking the Promise of Brown: The Resegregation of America's Schools 30 (2022). For all of us, in our time on this Court, that has never been more true than today. In overruling Roe and Casey, this Court betrays its guiding principles.

With sorrow—for this Court, but more, for the many millions of American women who have today lost a fundamental constitutional protection—we dissent.

APPENDIX

This Appendix analyzes in full each of the 28 cases the majority says support today's decision to overrule *Roe* v. *Wade*, 410 U. S. 113 (1973), and *Planned Parenthood of Southeastern Pa.* v. *Casey*, 505 U. S. 833 (1992). As explained herein, the Court in each case relied on traditional *stare decisis* factors in overruling.

A great many of the overrulings the majority cites involve a prior precedent that had been rendered out of step with or effectively abrogated by contemporary case law in light of intervening developments in the broader doctrine. See Ramos v. Louisiana, 590 U. S. ____, ___ (2020) (slip op., at 22) (holding the Sixth Amendment requires a unanimous jury verdict in state prosecutions for serious offenses, and overruling Apodaca v. Oregon, 406 U.S. 404 (1972), because "in the years since Apodaca, this Court ha[d] spoken inconsistently about its meaning" and had undercut its validity "on at least eight occasions"); Ring v. Arizona, 536 U. S. 584, 608–609 (2002) (recognizing a Sixth Amendment right to have a jury find the aggravating factors necessary to impose a death sentence and, in so doing, rejecting Walton v. Arizona, 497 U.S. 639 (1990), as overtaken by and irreconcilable with Apprendi v. New Jersey, 530 U.S. 466 (2000)); Agostini v. Felton, 521 U.S. 203, 235–236 (1997) (considering the Establishment Clause's constraint on government aid to religious instruction, and overruling Aguilar v. Felton, 473 U.S. 402 (1985), in light of several related doctrinal developments that had so undermined Aguilar and the assumption on which it rested as to render it no longer good law); Batson v. Kentucky, 476 U.S. 79, 93–96 (1986) (recognizing that a defendant may make a prima facie showing of purposeful racial discrimination in selection of a jury venire by relying solely on the facts in his case, and, based on subsequent developments in equal protection law, rejecting part of Swain v. Alabama, 380 U.S. 202 (1965), which had imposed a more demanding evidentiary

burden); Brandenburg v. Ohio, 395 U.S. 444, 447–448 (1969) (per curian) (holding that mere advocacy of violence is protected by the First Amendment, unless intended to incite it or produce imminent lawlessness, and rejecting the contrary rule in Whitney v. California, 274 U. S. 357 (1927), as having been "thoroughly discredited by later decisions"); Katz v. United States, 389 U. S. 347, 351, 353 (1967) (recognizing that the Fourth Amendment extends to material and communications that a person "seeks to preserve as private," and rejecting the more limited construction articulated in Olmstead v. United States, 277 U.S. 438 (1928), because "we have since departed from the narrow view on which that decision rested," and "the underpinnings of Olmstead . . . have been so eroded by our subsequent decisions that the 'trespass' doctrine there enunciated can no longer be regarded as controlling"); Miranda v. Arizona, 384 U.S. 436, 463-467, 479, n. 48 (1966) (recognizing that the Fifth Amendment requires certain procedural safeguards for custodial interrogation, and rejecting *Crooker* v. California, 357 U. S. 433 (1958), and Cicenia v. Lagay, 357 U. S. 504 (1958), which had already been undermined by Escobedo v. Illinois, 378 U. S. 478 (1964)); Malloy v. Hogan, 378 U.S. 1, 6-9 (1964) (explaining that the Fifth Amendment privilege against "self-incrimination is also protected by the Fourteenth Amendment against abridgment by the States," and rejecting Twining v. New Jersey, 211 U.S. 78 (1908), in light of a "marked shift" in Fifth Amendment precedents that had "necessarily repudiated" the prior decision); Gideon v. Wainwright, 372 U.S. 335, 343–345 (1963) (acknowledging a right to counsel for indigent criminal defendants in state court under the Sixth and Fourteenth Amendments, and overruling the earlier precedent failing to recognize such a right, Betts v. Brady, 316 U.S.

455 (1942));³¹ Smith v. Allwright, 321 U.S. 649, 659–662 (1944) (recognizing all-white primaries are unconstitutional after reconsidering in light of "the unitary character of the electoral process" recognized in *United States* v. Classic, 313 U.S. 299 (1941), and overruling Grovey v. Townsend, 295 U. S. 45 (1935)); United States v. Darby, 312 U. S. 100, 115–117 (1941) (recognizing Congress's Commerce Clause power to regulate employment conditions and explaining as "inescapable" the "conclusion . . . that Hammer v. Dagenhart, [247 U. S. 251 (1918)]," and its contrary rule had "long since been" overtaken by precedent construing the Commerce Clause power more broadly); Erie R. Co. v. Tompkins, 304 U.S. 64, 78-80 (1938) (applying state substantive law in diversity actions in federal courts and overruling Swift v. Tyson, 16 Pet. 1 (1842), because an intervening decision had "made clear" the "fallacy underlying the rule").

Additional cases the majority cites involved fundamental factual changes that had undermined the basic premise of the prior precedent. See *Citizens United* v. *Federal Election Comm'n*, 558 U. S. 310, 364 (2010) (expanding First Amendment protections for campaign-related speech and citing technological changes that undermined the distinctions of the earlier regime and made workarounds easy, and overruling *Austin* v. *Michigan Chamber of Commerce*, 494 U. S. 652 (1990), and partially overruling *McConnell* v. *Federal Election Comm'n*, 540 U. S. 93 (2003)); *Crawford* v. *Washington*, 541 U. S. 36, 62–65 (2004) (expounding on the Sixth Amendment right to confront witnesses and rejecting the prior framework, based on its practical failing to keep

³¹We have since come to understand *Gideon* as part of a larger doctrinal shift—already underway at the time of *Gideon*—where "the Court began to hold that the Due Process Clause fully incorporates particular rights contained in the first eight Amendments." *McDonald* v. *Chicago*, 561 U. S. 742, 763 (2010); see also *id.*, at 766.

out core testimonial evidence, and overruling *Ohio* v. *Roberts*, 448 U. S. 56 (1980)); *Mapp* v. *Ohio*, 367 U. S. 643, 651–652 (1961) (holding that the exclusionary rule under the Fourth Amendment applies to the States, and overruling the contrary rule of *Wolf* v. *Colorado*, 338 U. S. 25 (1949), after considering and rejecting "the current validity of the factual grounds upon which *Wolf* was based").

Some cited overrulings involved both significant doctrinal developments and changed facts or understandings that had together undermined a basic premise of the prior decision. See Janus v. State, County, and Municipal Employees, 585 U. S. ___, ___ (2018) (slip op., at 42, 47–49) (holding that requiring public-sector union dues from nonmembers violates the First Amendment, and overruling Abood v. Detroit Bd. of Ed., 431 U. S. 209 (1977), based on "both factual and legal" developments that had "eroded the decision's underpinnings and left it an outlier among our First Amendment cases" (internal quotation marks omitted)); Obergefell v. Hodges, 576 U.S. 644, 659–663 (2015) (holding that the Fourteenth Amendment protects the right of same-sex couples to marry in light of doctrinal developments, as well as fundamentally changed social understanding); Lawrence v. Texas, 539 U. S. 558, 572–578 (2003) (overruling Bowers v. Hardwick, 478 U.S. 186 (1986), after finding anti-sodomy laws to be inconsistent with the Fourteenth Amendment in light of developments in the legal doctrine, as well as changed social understanding of sexuality); United States v. Scott, 437 U. S. 82, 101 (1978) (overruling United States v. Jenkins, 420 U.S. 358 (1975), three years after it was decided, because of developments in the Court's double jeopardy case law, and because intervening practice had shown that government appeals from midtrial dismissals requested by the defendant were practicable, desirable, and consistent with double jeopardy values); Craig v. Boren, 429 U. S. 190, 197–199, 210, n. 23 (1976) (holding that sex-based classifications are subject to intermediate scrutiny under the Fourteenth Amendment's Equal Protection Clause, including because *Reed* v. *Reed*, 404 U. S. 71 (1971), and other equal protection cases and social changes had overtaken any "inconsistent" suggestion in *Goesaert* v. *Cleary*, 335 U. S. 464 (1948)); *Taylor* v. *Louisiana*, 419 U. S. 522, 535–537 (1975) (recognizing as "a foregone conclusion from the pattern of some of the Court's cases over the past 30 years, as well as from legislative developments at both federal and state levels," that women could not be excluded from jury service, and explaining that the prior decision approving such practice, *Hoyt* v. *Florida*, 368 U. S. 57 (1961), had been rendered inconsistent with equal protection jurisprudence).

Other overrulings occurred very close in time to the original decision so did not engender substantial reliance and could not be described as having been "embedded" as "part of our national culture." Dickerson v. United States, 530 U. S. 428, 443 (2000); see Payne v. Tennessee, 501 U. S. 808 (1991) (revising procedural rules of evidence that had barred admission of certain victim-impact evidence during the penalty phase of capital cases, and overruling South Carolina v. Gathers, 490 U.S. 805 (1989), and Booth v. Maryland, 482 U.S. 496 (1987), which had been decided two and four years prior, respectively); Seminole Tribe of Fla. v. Florida, 517 U. S. 44 (1996) (holding that Congress cannot abrogate state-sovereign immunity under its Article I commerce power, and rejecting the result in *Pennsylvania* v. Union Gas Co., 491 U.S. 1 (1989), seven years later; the decision in *Union Gas* never garnered a majority); *Garcia* v. San Antonio Metropolitan Transit Authority, 469 U.S. 528, 531 (1985) (holding that local governments are not constitutionally immune from federal employment laws, and overruling National League of Cities v. Usery, 426 U. S. 833 (1976), after "eight years" of experience under that regime showed *Usery*'s standard was unworkable and, in practice, undermined the federalism principles the decision sought

Appendix to opinion of BREYER, SOTOMAYOR, and KAGAN, JJ.

to protect).

The rest of the cited cases were relatively minor in their effect, modifying part or an application of a prior precedent's test or analysis. See Montejo v. Louisiana, 556 U.S. 778 (2009) (citing workability and practical concerns with additional layers of prophylactic procedural safeguards for defendants' right to counsel, as had been enshrined in Michigan v. Jackson, 475 U. S. 625 (1986)); Illinois v. Gates, 462 U. S. 213, 227–228 (1983) (replacing a two-pronged test under Aguilar v. Texas, 378 U.S. 108 (1964), and Spinelli v. United States, 393 U.S. 410 (1969), in favor of a traditional totality-of-the-circumstances approach to evaluate probable cause for issuance of a warrant); Wesberry v. Sanders, 376 U. S. 1, 4 (1964), and Baker v. Carr, 369 U. S. 186, 202 (1962) (clarifying that the "political question" passage of the minority opinion in Colegrove v. Green, 328 U.S. 549 (1946), was not controlling law).

In sum, none of the cases the majority cites is analogous to today's decision to overrule 50- and 30-year-old watershed constitutional precedents that remain unweakened by any changes of law or fact.

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, et al.,

Plaintiffs,

v. 2:22-CV-223-Z

U.S. FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

Before the Court is Plaintiffs' Motion for Preliminary Injunction ("Motion") (ECF No. 6), filed on November 18, 2022. The Court **GRANTS** the Motion **IN PART**.

BACKGROUND

Over twenty years ago, the United States Food and Drug Administration ("FDA") approved chemical abortion ("2000 Approval"). The legality of the 2000 Approval is now before this Court. Why did it take *two decades* for judicial review in federal court? After all, Plaintiffs' petitions challenging the 2000 Approval date back to the year 2002, right?

Simply put, FDA stonewalled judicial review — until now. Before Plaintiffs filed this case, FDA ignored their petitions for over sixteen years, even though the law requires an agency response within "180 days of receipt of the petition." 21 C.F.R. § 10.30(e)(2)). But FDA waited 4,971 days to adjudicate Plaintiffs' first petition and 994 days to adjudicate the second. *See* ECF Nos. 1-14, 1-28, 1-36, 1-44 ("2002 Petition," "2019 Petition," respectively). Had FDA responded to Plaintiffs' petitions within the 360 total days allotted, this case would have been in federal court *decades* earlier. Instead, FDA postponed and procrastinated for nearly **6,000 days**.

Plaintiffs are doctors and national medical associations that provide healthcare for pregnant and post-abortive women and girls. Plaintiffs sued Defendants to challenge multiple administrative actions culminating in the 2000 Approval of the chemical abortion regimen for mifepristone. ECF No. 1 at 2. Mifepristone — also known as RU-486 or Mifeprex — is a synthetic steroid that blocks the hormone progesterone, halts nutrition, and ultimately starves the unborn human until death. ECF No. 7 at 7–8. Because mifepristone alone will not always complete the abortion, FDA mandates a two-step drug regimen: mifepristone to kill the unborn human, followed by misoprostol to induce cramping and contractions to expel the unborn human from the mother's womb. *Id.* at 8.

In 1996, the Population Council² filed a new drug application ("NDA") with FDA for mifepristone. ECF No. 1 at 35. Shortly thereafter, FDA reset the NDA from "standard" to "priority review." *Id.* In February 2000, FDA wrote a letter to the Population Council stating that "adequate information ha[d] *not* been presented to demonstrate that the drug, when marketed in accordance with the terms of distribution proposed, is safe and effective for use as recommended." ECF No. 1-24 at 6 (emphasis added). FDA also noted the "restrictions on distribution will need to be amended." *Id.*

¹ Jurists often use the word "fetus" to inaccurately identify unborn humans in *un*scientific ways. The word "fetus" refers to a specific gestational stage of development, as opposed to the zygote, blastocyst, or embryo stages. *See* ROBERT P. GEORGE & CHRISTOPHER TOLLEFSEN, EMBRYO 27–56 (2008) (explaining the gestational stages of an unborn human). Because other jurists use the terms "unborn human" or "unborn child" interchangeably, and because both terms are inclusive of the multiple gestational stages relevant to the FDA Approval, 2016 Changes, and 2021 Changes, this Court uses "unborn human" or "unborn child" terminology throughout this Order, as appropriate.

² The Population Council was founded by John D. Rockefeller in 1952 after he convened a conference with "population activists" such as Planned Parenthood's director and several well-known eugenicists.

MATTHEW CONNELLY, FATAL MISCONCEPTION: THE STRUGGLE TO CONTROL WORLD POPULATION 156 (2008). The conference attendees discussed "the problem of 'quality." John D. Rockefeller, *On the Origins of the Population Council*, 3 POPULATION AND DEV. REV. 493, 496 (1977). They concluded that "[m]odern civilization had reduced the operation of natural selection by saving more 'weak' lives and enabling them to reproduce," thereby resulting in "a downward trend in . . . genetic quality." *Id*.

Mere months later, FDA approved the chemical abortion regimen under Subpart H, commonly known as "accelerated approval" and originally designed to expedite investigational HIV medications during the AIDS epidemic.³ Subpart H accelerates approval of drugs "that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments (*e.g.*, ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy)." 21 C.F.R. § 314.500.

FDA then imposed post-approval restrictions "to assure safe use." *See* 21 C.F.R. § 314.520. These restrictions were later adopted when Subpart H was codified as a Risk Evaluation and Mitigation Strategy ("REMS") "to ensure that the benefits of the drug outweigh the risks." 21 U.S.C. § 355-1(a)(1)–(2). The drugs were limited to women and girls with unborn children aged seven-weeks gestation or younger. ECF No. 7 at 9. FDA also required three (3) in-person office visits: the first to administer mifepristone, the second to administer misoprostol, and the third to assess any complications and ensure there were no fetal remains in the womb. *Id.* Additionally, abortionists were required to be properly trained to administer the regimen and to report *all* adverse events from the drugs. *Id.*

Plaintiffs American Association of Pro-Life Obstetricians & Gynecologists ("AAPLOG") and Christian Medical & Dental Associations filed the 2002 Petition with FDA challenging the 2000 Approval. *Id.* In 2006, the U.S. House Subcommittee on Criminal Justice, Drug Policy, and Human Resources expressed the same concerns and held a hearing to investigate FDA's handling

³ See, e.g., Jessica Holden Kloda & Shahza Somerville, FDA's Expedited Review Process: The Need for Speed, 35 APPLIED CLINICAL TRIALS 17, 17–18 (2015) ("In 1992, in response to a push by AIDS advocates to make the investigational anti-AIDS drug azidothymidine (AZT) accessible, the FDA enacted 'Subpart H' commonly referred to as accelerated approval; giving rise to expedited review of drugs by the FDA.").

of mifepristone and its subsequent monitoring of the drug.⁴ Then-Chairman Souder remarked that mifepristone was "associated with the deaths of at least 8 women, 9 life-threatening incidents, 232 hospitalizations, 116 blood transfusions, and 88 cases of infection." Additionally, Chairman Souder noted "more than 950 adverse event cases" associated with mifepristone "out of only 575,000 prescriptions, at most. The subsequent Staff Report concluded that FDA's approval and monitoring of mifepristone was "substandard and necessitates the withdrawal of this dangerous and fatal product before more women suffer the known and anticipated consequences or fatalities." The report stated the "unusual approval" demonstrated a lower standard of care for women, "and [mifepristone's] withdrawal from the market is justified and necessary to protect the public's health."

FDA rejected the 2002 Petition on March 29, 2016 — nearly *fourteen* years after it was filed. ECF No. 7 at 9. That same day, FDA approved several changes to the chemical abortion drug regimen, including the removal of post-approval safety restrictions for pregnant women and girls. *Id.* at 10. FDA increased the maximum gestational age from seven-weeks gestation to ten-weeks gestation. *Id.* And FDA also: (1) changed the dosage for chemical abortion; (2) reduced the number of required in-person office visits from three to one; (3) allowed non-doctors to prescribe and administer chemical abortions; and (4) eliminated the requirement for prescribers to report non-fatal adverse events from chemical abortion. *Id.*

⁴ See The FDA and RU-486: Lowering the Standard for Women's Health: Hearing Before the Subcomm. on Crim. Just., Drug Pol'y, & Hum. Res. of the H. Comm. on Gov't Reform, 109th Cong. 3 (2006) ("Subcommittee Report").

⁵ The transcript of the hearing before the House Subcommittee is available at https://www.govinfo.gov/content/pkg/CHRG-109hhrg31397/html/CHRG-109hhrg31397.htm.

⁶ *Id*.

⁷ Subcommittee Report at 40.

⁸ *Id*.

In March 2019, Plaintiffs AAPLOG and American College of Pediatricians filed the 2019 Petition challenging FDA's 2016 removal of safety restrictions. *Id.* On April 11, 2019, FDA approved GenBioPro, Inc.'s abbreviated new drug application ("ANDA") for a generic version of mifepristone without requiring or reviewing *new* peer-reviewed science ("2019 Generic Approval"). *Id.* Two years later, on April 12, 2021, FDA announced it would "exercise enforcement discretion" to allow "dispensing of mifepristone through the mail . . . or through a mail-order pharmacy" during the COVID pandemic — notwithstanding the nearly 150-year-old Comstock Act banning the *mailing* of "[e]very article, instrument, substance, drug, medicine or thing" that produces "abortion." *Id.* Finally, on December 16, 2021, FDA denied most of Plaintiff's 2019 Petition. *Id.* at 11. Specifically, FDA expressly rejected the 2019 Petition's request to keep the in-person dispensing requirements and announced that the agency would *permanently* allow chemical abortion by mail. *Id.*

After Plaintiffs filed suit, Danco Laboratories, LLC ("Danco") — the holder of the NDA for mifepristone — moved to intervene as a defendant. ECF No. 19. On February 6, 2023, this Court granted Danco's motion. ECF No. 33. Plaintiffs now seek a preliminary injunction ordering Defendants to withdraw or suspend: (1) FDA's 2000 Approval and 2019 Approval of mifepristone tablets, 200 mg, thereby removing both from the list of Approved Drugs; (2) FDA's 2016 Changes and 2019 Generic Approval; and (3) FDA's April 12, 2021, Letter and December 16, 2021, Response to the 2019 Petition concerning the in-person dispensing requirement for mifepristone. ECF No. 7 at 12. Additionally, Plaintiffs seek to enjoin Defendants from taking actions inconsistent with these orders. *Id*.

LEGAL STANDARD

A court may issue a preliminary injunction when a movant satisfies the following four factors: (1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable harm if the injunction does not issue; (3) the threatened injury outweighs any harm that will result if the injunction is granted; and (4) the grant of an injunction is in the public interest. *See Louisiana v. Becerra*, 20 F.4th 260, 262 (5th Cir. 2021). "The purpose of a preliminary injunction is always to prevent irreparable injury so as to preserve the court's ability to render a meaningful decision on the merits." *Canal Auth. of State of Fla. v. Callaway*, 489 F.2d 567, 576 (5th Cir. 1974). The same standards apply "to prevent irreparable injury" under the Administrative Procedure Act ("APA"). *See* 5 U.S.C. § 705; *Wages & White Lion Invs., L.L.C. v. U.S. Food & Drug Admin.*, 16 F.4th 1130, 1143 (5th Cir. 2021).

ANALYSIS

A. Plaintiffs Have Standing

The judicial power of federal courts is limited to certain "Cases" and "Controversies." U.S. CONST. art. III, § 2. The case-or-controversy requirement requires a plaintiff to establish he has standing to sue. *See Cibolo Waste, Inc. v. City of San Antonio*, 718 F.3d 469, 473 (5th Cir. 2013). To have standing, the party invoking federal jurisdiction must show: "(i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021). Courts should assess whether the alleged injury to the plaintiff has a "close relationship" to harm "traditionally" recognized as providing a basis for a lawsuit in American courts. *Id.* at 2204. "[S]tanding is not dispensed in

gross; rather, plaintiffs must demonstrate standing for each claim that they press and for each form of relief that they seek (for example, injunctive relief and damages)." *Id.* at 2208.

1. Plaintiff Medical Associations have Associational Standing

"An association or organization can establish an injury-in-fact through either of two theories, appropriately called 'associational standing' and 'organizational standing." *OCA-Greater Hous. v. Texas*, 867 F.3d 604, 610 (5th Cir. 2017). Under a theory of "associational standing," an association "has standing to bring a suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests at stake are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Tex. Ass'n of Mfrs. v. U.S. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 377 (5th Cir. 2021) (quoting *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000)).

Here, the associations' members have standing because they allege adverse events from chemical abortion drugs can overwhelm the medical system and place "enormous pressure and stress" on doctors during emergencies and complications. ECF No. 7 at 14. These emergencies "consume crucial limited resources, including blood for transfusions, physician time and attention, space in hospital and medical centers, and other equipment and medicines. ECF No. 1-5 at 9. This is especially true in maternity-care "deserts" — geographical areas with limited physician availability. *Id.* These emergencies force doctors into situations "in which they feel complicit in the elective chemical abortion by needing to remove a baby with a beating heart or pregnancy

⁹ See James Studnicki et al., A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999-2015, 8 HEALTH SERV. RSCH. MGMT. EPIDEMIOLOGY 8 (2021) ("ER visits following mifepristone abortion grew from 3.6% of all postabortion visits in 2002 to 33.9% of all postabortion visits in 2015. The trend toward increasing use of mifepristone abortion requires all concerned with health care utilization to carefully follow the ramifications of ER utilization.").

tissue as the only means to save the life of the woman or girl." ECF No. 1 at 85. Members of Plaintiff medical associations "oppose being forced to end the life of a human being in the womb for no medical reason, including by having to complete an incomplete elective chemical abortion." *Id.* at 86; *see also Texas v. Becerra*, No. 5:22-CV-185-H, 2022 WL 3639525, at *12 (N.D. Tex. Aug. 23, 2022) (unwanted participation in elective abortions is cognizable under Article III).

Plaintiffs also argue the challenged actions "prevent Plaintiff doctors from practicing evidence-based medicine" and have caused Plaintiffs to face increased exposure to allegations of malpractice and potential liability, along with higher insurance costs. ECF No. 7 at 15. The lack of information on adverse events "harms the doctor-patient relationship" because women and girls are prevented from giving informed consent to providers. *Id.*; *see also* American Medical Association Code of Medical Ethics, *Opinion 2.1.1: Informed Consent* (informed consent is "fundamental in both ethics and law"). To obtain informed consent, physicians must "[a]ssess the patient's ability to understand relevant medical information" and present to their patient "relevant information accurately and sensitively," including the burdens and risks of the procedure. *Id.*

Women also perceive the harm to the informed-consent aspect of the physician-patient relationship. In one study, fourteen percent of women and girls reported having received insufficient information about (1) side effects, (2) the intensity of the cramping and bleeding, (3) the next steps after expelling the aborted human, and (4) potential negative emotional reactions like fear, uncertainty, sadness, regret, and pain. See Katherine A. Rafferty & Tessa Longbons, #AbortionChangesYou: A Case Study to Understand the Communicative Tensions in Women's Medication Abortion Narratives, 36 **HEALTH** COMMC'N. 1485, 1485-94 (2021). Plaintiff physicians' lack of pertinent information on chemical abortion harms their physician-patient relationships because they cannot receive informed consent from the women and girls they treat in their clinics. Plaintiffs allege these actions have "radically altered the standard of care." ECF No. 1-6 at 7.

Additionally, Plaintiff medical associations have associational standing via their members' third-party standing to sue on behalf of their patients. See N.Y. State Club Ass'n, Inc. v. City of New York, 487 U.S. 1, 9 (1988) ("It does not matter what specific analysis is necessary to determine that the members could bring the same suit."); Pa. Psychiatric Soc. v. Green Spring Health Servs., Inc., 280 F.3d 278, 293 (3d Cir. 2002) ("So long as the association's members have or will suffer sufficient injury to merit standing and their members possess standing to represent the interests of third-parties, then associations can advance the third-party claims of their members without suffering injuries themselves."); Ohio Ass'n of Indep. Schs. v. Goff, 92 F.3d 419, 422 (6th Cir. 1996) (associational standing via member schools' third-party standing to assert constitutional rights of parents to direct their children's education); 13A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 3531.9.3 (3d ed. 2022) ("Doctors regularly achieve standing to protect the rights of patients and their own related professional rights.").

The requirements for third-party standing are met here because: (1) the patients have "endure[d] many intense side effects and suffer[ed] significant complications requiring medical attention" and "suffer distress and regret"; ¹⁰ (2) the patients have a "close relation" to the physician members of the Plaintiff medical associations; and (3) "some hindrance" exists to the patients' ability to protect their interests. *See* ECF No. 7 at 13; *Powers v. Ohio*, 499 U.S. 400, 410–11 (1991); *Singleton v. Wulff*, 428 U.S. 106, 117 (1976) (women seeking abortions may be chilled "by a desire to protect the very privacy of [their] decision from the publicity of a court suit");

¹⁰ *Cf. TransUnion*, 141 S. Ct. at 2211 ("Nor did those plaintiffs present evidence that . . . they suffered some other injury (such as an emotional injury)"); *Denney v. Deutsche Bank AG*, 443 F.3d 253, 265 (2d Cir. 2006).

Pa. Psychiatric, 280 F.3d at 290 ("[A] party need not face insurmountable hurdles to warrant third-party standing."). The injuries suffered by patients of the Plaintiff medical associations' members are sufficient to confer associational standing.

Here, the physician-patient dynamic favors third-party standing. Unlike abortionists suing on behalf of women seeking abortions, here there are no potential conflicts of interest between the Plaintiff physicians and their patients. See June Med. Servs. L.L.C. v. Russo, 140 S. Ct. 2103, 2167 (2020) (Alito, J., dissenting), abrogated by Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228 (2022) (abortionists have a "financial interest in avoiding burdensome regulations," while women seeking abortions "have an interest in the preservation of regulations that protect their health"). And the case for a close physician-patient relationship is even stronger here than in the abortion context. See id. at 2168 ("[A] woman who obtains an abortion typically does not develop a close relationship with the doctor who performs the procedure. On the contrary, their relationship is generally brief and very limited."); see also ECF No. 1-9 at 7 ("[I]n many cases there is no doctor-patient relationship [between a woman and an abortionist], so [women] often present to overwhelmed emergency rooms in their distress, where they are usually cared for by physicians other than the abortion prescriber."); ECF No. 1-11 at 4 (because there "is no follow-up or additional care provided to patients" by abortionists, there is "no established relationship with a physician" and "patients are simply left to report to the emergency room"). Plaintiff physicians often spend several hours treating post-abortive women, even hospitalizing them overnight or providing treatment throughout several visits. See ECF No. 1-8 at 5-6. Given the Supreme Court's jurisprudence on the close relationship between abortionists and women, the facts of this case indicate that Plaintiffs' relationships with their patients are at least as close — if not closer — for purposes of third-party standing.

Finally, women who have *already* obtained an abortion may be *more* hindered than women who challenge restrictions on abortion. Women who have aborted a child — especially through chemical abortion drugs that necessitate the woman seeing her aborted child once it passes — often experience shame, regret, anxiety, depression, drug abuse, and suicidal thoughts because of the abortion. See ECF No. 96 at 25; David C. Reardon et al., Deaths Associated with Pregnancy Outcome: A Record Linkage Study of Low Income Women, 95 S. MED. J. 834, 834–41 (2002) (women who receive abortions have a 154% higher risk of death from suicide than if they gave birth, with persistent tendencies over time and across socioeconomic boundaries, indicating "selfdestructive tendencies, depression, and other unhealthy behavior aggravated by the abortion experience"); Priscilla K. Coleman, Abortion and Mental Health: Quantitative Synthesis and Analysis of Research Published 1995–2009, 199 British J. Psychiatry 180, 180–86 (2011) (same). Subsequently, in addition to the typical privacy concerns present in third-party standing in abortion cases, adverse abortion experiences that are often deeply traumatizing pose a hindrance to a woman's ability to bring suit. In short, Plaintiffs — rather than their patients — are most likely the "least awkward challenger[s]" to Defendants' actions. Craig v. Boren, 429 U.S. 190, 197 (1976).

2. Plaintiff Medical Associations have Organizational Standing

"[O]rganizational standing' does not depend on the standing of the organization's members." *OCA*, 867 F.3d at 610. The organization can establish standing in its own name if it "meets the same standing test that applies to individuals." *Id.* (internal marks omitted). An organization can have standing if it has "proven a drain on its resources resulting from counteracting the effects of the defendant's actions." *La. ACORN Fair Hous. v. LeBlanc*, 211 F.3d 298, 305 (5th Cir. 2000); *see also Zimmerman v. City of Austin, Tex.*, 881 F.3d 378, 390 (5th Cir.

2018) (changing one's "plans or strategies in response to an allegedly injurious law can itself be a sufficient injury to confer standing"). "Such concrete and demonstrable injury to the organization's activities—with the consequent drain on the organization's resources—constitutes far more than simply a setback to the organization's abstract social interests." *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982) (internal marks omitted).

One way an organization can establish standing is by "identifying specific projects that [it] had to put on hold or otherwise curtail in order to respond to the [challenged action]." *Tex. State LULAC v. Elfant*, 52 F.4th 248, 253 (5th Cir. 2022) (internal marks omitted). This is "not a heightening of the *Lujan* standard, 11 but an example of how to satisfy it by pointing to a non-litigation-related expense." *OCA*, 867 F.3d at 612. Plaintiffs "need not identify specific projects that they have placed on hold or otherwise curtailed." 12 La Unión del Pueblo Entero v. Abbott, No. 5:21-CV-0844-XR, 2022 WL 3052489, at *31 (W.D. Tex. Aug. 2, 2022). Rather, this is simply the "most secure foundation" to establish organizational standing. 13A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 3531.9.5 (3d ed. 2022). Furthermore, "[a]t the pleading stage," we 'liberally' construe allegations of injury." *Bezet v. United States*, 714 Fed. Appx. 336, 339 (5th Cir. 2017) (quoting *Little v. KPMG LLP*, 575 F.3d 533, 540 (5th Cir. 2009)).

Here, Plaintiff medical associations have standing via diversionary injury. Because of FDA's failure to require reporting of all adverse events, Plaintiffs allege FDA's actions have frustrated their ability to educate and inform their member physicians, their patients, and the public on the dangers of chemical abortion drugs. ECF No. 7 at 12. As a result, Plaintiffs attest they have

¹¹ See Lujan v. Defs. of Wildlife, 504 U.S. 555 (1992).

¹² At the hearing, Danco argued *Elfant* held there was no standing where organizations failed to identify specific projects put on hold. ECF No. 136 at 125. This is incorrect. The Fifth Circuit in *Elfant* assumed without deciding the plaintiffs pled an injury-in-fact but held they did not have standing because the causation and redressability elements were not met. *See* 52 F.4th at 255.

diverted valuable resources away from advocacy and educational efforts to compensate for the lack of information. *See* ECF No. 1 at 91. Such diversions expend considerable time, energy, and resources, to the detriment of other priorities and functions and impair Plaintiffs' ability to carry out their educational purpose. *Id.* at 92; *N.A.A.C.P. v. City of Kyle, Tex.*, 626 F.3d 233, 238 (5th Cir. 2010). Similarly, Plaintiffs allege their efforts to respond to FDA's actions have "tak[en] them away from other priorities such as fundraising and membership recruitment and retention." ECF Nos. 1-4 at 6, 1-5 at 11. Consequently, Plaintiffs have re-calibrated their outreach efforts to spend extra time and money educating their members about the dangers of chemical abortion drugs. Combined, these facts are sufficient to confer organizational standing. *See OCA*, 867 F.3d at 612 (finding organizational standing even where the injury "was not large"); *Fowler*, 178 F.3d at 356 (injuries in fact "need not measure more than an 'identifiable trifle'") (internal marks omitted).

3. Plaintiffs' alleged Injuries are Concrete and Redressable

Defendants contend that Plaintiffs' theories of standing "depend upon layer after layer of speculation." ECF No. 28 at 20. But Plaintiffs allege FDA's chemical abortion regimen "caused" intense side effects and significant complications for their patients requiring medical intervention and attention. ECF No. 7 at 13; *see id.* ("The harms that the FDA has wreaked on women and girls have also injured, and will continue to injure, Plaintiff doctors and their medical practices."); *id.* at 14 ("The FDA's actions have placed enormous pressure and stress on Plaintiff doctors during these

¹³ It is true that Plaintiffs must allege their activities in response to the challenged actions differ from their "routine" activities. *See, e.g., City of Kyle*, 626 F.3d at 238. But Plaintiffs have done so. For example, Plaintiffs argue they conducted independent studies and analyses of available data to the detriment of their advocacy, educational, and recruitment efforts. ECF No. 1-8 at 8. The Fifth Circuit has found diversionary injuries to constitute injuries-in-fact even where it was less clear the plaintiffs diverted from routine activities. *See Ass'n of Cmty. Orgs. for Reform Now v. Fowler*, 178 F.3d 350, 360 (5th Cir. 1999) (injury-in-fact where organization regularly conducted voter registration drives and "expended resources registering voters in low registration areas who would have already been registered" if not for the challenged actions).

emergency situations."); *id.* at 15 ("The FDA has caused Plaintiff doctors to face increased exposure to allegations of malpractice and potential liability, along with higher insurance costs."). In fact, Plaintiffs' declarations list specific events where Plaintiff physicians provided emergency care to women suffering from chemical abortion. *See* ECF Nos. 1-8 at 5–6, 1-9 at 4–9, 1-10 at 6–7, 1-11 at 5–6. And Defendants even concede the existence of adverse events related to chemical abortion drugs. *See* ECF No. 28 at 21. Consequently, Defendants misconstrue Plaintiffs' pleadings and mischaracterize Plaintiffs' evidence as "speculative." It is not.

Past injuries thus distinguish this case from Clapper v. Amnesty Int'l USA, where the Supreme Court held a "threatened injury must be certainly impending to constitute injury in fact." 568 U.S. 398, 410 (2013) (quoting Whitmore v. Arkansas, 495 U.S. 149, 157–58 (1990)). Were there no past injuries in this case, the alleged future harms are still less attenuated than those in Clapper. See id. (finding "a highly attenuated chain of" five separate possibilities needed to align for the alleged harm to occur); McCardell v. U.S. Dep't of Hous. & Urb. Dev., 794 F.3d 510, 520 (5th Cir. 2015) ("[U]nlike in *Clapper*, where the alleged injury depended on a long and tenuous chain of contingent events, the chain-of-events framework in this case involves fewer steps and no unfounded assumptions.") (internal marks omitted). See also ECF No. 1-31 at 10 (roughly eight percent of women who use abortion pills will require surgical abortion); ECF No. 1-14 at 23 (discussing a study in which 18.3 percent of women required surgical intervention after chemical abortion). And as post-Whitmore cases have demonstrated, the "certainly impending" standard for an "imminent" injury is not as demanding as it sounds. See TransUnion, 141 S. Ct. at 2197 (material risk of future harm can suffice "so long as the risk of harm is sufficiently imminent and substantial"); Susan B. Anthony List v. Driehaus, 573 U.S. 149, 158 (2014) ("An allegation of future injury may suffice if the threatened injury is 'certainly impending,' or there is a 'substantial risk' that the harm will occur.") (emphasis added); *Clapper*, 568 U.S. at 414 n.5; *Massachusetts v*. *E.P.A.*, 549 U.S. 497, 526 n.23 (2007) ("Even a small probability of injury is sufficient . . . provided of course that the relief sought would, if granted, reduce the probability."); *Deanda v. Becerra*, No. 2:20-CV-092-Z, 2022 WL 17572093, at *2 (N.D. Tex. Dec. 8, 2022) (collecting cases). ¹⁴

For similar reasons, Defendants' reliance on *City of Los Angeles v. Lyons* also fails. 461 U.S. 95 (1983). There, the Supreme Court held Lyons did not have standing to seek injunctive relief because "[t]here was no finding that Lyons faced a real and immediate threat of again being illegally choked" by Los Angeles police. *Id.* at 110. The *Lyons* holding "is based on the obvious proposition that a prospective remedy will provide no relief for an injury that is, and likely will remain, entirely in the past." *Am. Postal Workers Union v. Frank*, 968 F.2d 1373, 1376 (1st Cir. 1992). "No such reluctance, however, is warranted here." *Hernandez v. Cremer*, 913 F.2d 230, 234 (5th Cir. 1990). Considering FDA's 2021 decision to permit "mail-in" chemical abortion, many women and girls will consume mifepristone without physician supervision. And in maternity-care "deserts," women may not have ready access to emergency care. In sum, there are fewer safety restrictions for women and girls today than ever before. Plaintiffs have good reasons to believe their alleged injuries will continue in the future, and possibly with greater frequency than in the past.

¹⁴ Defendants' reliance on *Spokeo, Inc. v. Robins* is also unavailing. 578 U.S. 330 (2016). Courts should indeed assess whether the alleged injury to the plaintiff has a "close relationship" to harm "traditionally" recognized as the basis for a lawsuit in American courts. *See TransUnion*, 141 S. Ct. at 2204. But "a plaintiff doesn't need to demonstrate that the level of harm he has suffered would be actionable under a similar, common-law cause of action." *Perez v. McCreary, Veselka, Bragg & Allen, P.C.*, 45 F.4th 816, 822 (5th Cir. 2022). Rather, Plaintiffs only need to show the *type* of harm allegedly suffered "is similar in kind to a type of harm that the common law has recognized as actionable." *Id.*; *see also Campaign Legal Ctr. v. Scott*, 49 F.4th 931, 940 (5th Cir. 2022) (Ho., J, concurring) (evidence of injury required by *TransUnion* is not burdensome). Harm resulting from unsafe drugs is similar to harm actionable under the common law.

Defendants next argue Plaintiffs' theories depend on "unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict." ECF No. 28 at 20 (quoting *Lujan*, 504 U.S. at 562). "[A] plaintiff must allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *Allen v. Wright*, 468 U.S. 737, 751 (1984), *abrogated on other grounds by Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 134 (2014); *see also Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41–42 (1976) ("In other words, the 'case or controversy' limitation of Art. III still requires that a federal court act only to redress injury that fairly can be traced to the challenged action of the defendant, and not injury that results from the independent action of some third party not before the court.").

In this case, a favorable decision would likely relieve Plaintiffs of at least some of the injuries allegedly caused by FDA. *See Larson v. Valente*, 456 U.S. 228, 243 n.15 (1982) ("[Plaintiffs] need not show that a favorable decision will relieve [their] *every* injury."); *Duke Power Co. v. Carolina Env't Study Grp., Inc.*, 438 U.S. 59, 74–75 (1978) (a "substantial likelihood" of the requested relief redressing the alleged injury is enough); *Sanchez v. R.G.L.*, 761 F.3d 495, 506 (5th Cir. 2014) (a plaintiff "need only show that a favorable ruling could potentially lessen its injury"); *Texas v. Becerra*, 577 F. Supp. 3d 527, 560 (N.D. Tex. 2021) ("That the plaintiffs have brought forth specific evidence and examples of how they *will* be harmed . . . distinguishes this case from others where a third party's actions *might* have hurt the plaintiff."). And redressability is satisfied even if relief must filter downstream through third parties uncertain to comply with the result, provided the relief would either: (1) remove an obstacle for a nonparty to act in a way favorable to the plaintiff; or (2) influence a nonparty to act in such a way. *See*, *e.g.*, *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2565–66 (2019) ("[T]hird parties will likely react in

predictable ways."); *Bennett v. Spear*, 520 U.S. 154, 169 (1997) (defendants' actions need not be "the very last step in the chain of causation"); *Larson*, 456 U.S. at 242–44; *NiGen Biotech, L.L.C.* v. *Paxton*, 804 F.3d 389, 396–98 (5th Cir. 2015). Therefore, Plaintiffs' alleged injuries are fairly traceable to Defendants and redressable by a favorable decision.

4. Plaintiffs are within the "Zone of Interests"

Plaintiffs are also within the zone of interests of the Federal Food, Drug, and Cosmetic Act ("FFDCA") and the Comstock Act. Plaintiffs suing under the APA must assert an interest that is "arguably within the zone of interests to be protected or regulated by the statute that they say was violated." *Texas v. United States*, 809 F.3d 134, 162 (5th Cir. 2015) (internal marks omitted). The zone-of-interests test "is not meant to be especially demanding" and is applied "in keeping with Congress's evident intent when enacting the APA to make agency action presumptively reviewable." *Id.* (internal marks omitted). The zone-of-interests test "looks to the law's substantive provisions to determine what interests (and hence which plaintiffs) are protected." *Simmons v. UBS Fin. Servs., Inc.*, 972 F.3d 664, 669 (5th Cir. 2020). "That interest, at times, may reflect aesthetic, conservational, and recreational as well as economic values." *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp.*, 397 U.S. 150, 154 (1970).

A federal court's obligation to hear and decide cases within its jurisdiction is "virtually unflagging." *Lexmark*, 572 U.S. at 126 (internal marks omitted). And "the trend is toward enlargement of the class of people who may protest administrative action." *Camp*, 397 U.S. at 154. No "explicit statutory provision" is necessary to confer standing. *Id.* at 155. "The test forecloses suit only when a plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *Texas v. United States*, 809 F.3d at 162 (internal marks omitted). In other words, "[t]here is

no presumption against judicial review and in favor of administrative absolutism unless that purpose is fairly discernible in the statutory scheme." *Camp*, 397 U.S. at 157 (internal marks omitted); *see also Barlow v. Collins*, 397 U.S. 159, 165 (1970) (courts "must decide if Congress has in express or implied terms precluded judicial review or committed the challenged action entirely to administrative discretion").

Defendants argue that Plaintiffs identify no particular provision of the FFDCA protecting their interests. ECF No. 28 at 26. But Plaintiffs' interests are *not* "marginally related" to the purposes implicit in the FFDCA. The statute's substantive provisions protect the safety of physicians' patients and the integrity of the physician-patient relationship. *See generally* 21 U.S.C. § 355. Furthermore, this Court finds Plaintiffs have third-party standing on behalf of their patients. Plaintiffs' patients are within the zone of interest of the FFDCA because patients seek safe and effective medical procedures.

Likewise, Plaintiffs are within the zone of interests of the Comstock Act. This statute "indicates a national policy of discountenancing abortion as inimical to the national life." *Bours v. United States*, 229 F. 960, 964 (7th Cir. 1915); *see also Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 71 n.19 (1983) (the "thrust" of the Comstock Act was "to prevent the mails from being used to corrupt the public morals"). There is no evidence that Congress "sought to preclude judicial review of administrative rulings" by FDA "as to the legitimate scope of activities" available concerning chemical abortion drugs under these statutes. *Camp*, 397 U.S. at 157. For all the aforementioned reasons, Plaintiffs have standing.

B. Plaintiffs' Claims Are Reviewable

Defendants aver that "[a]ll of Plaintiffs' claims are untimely or unexhausted except their challenge to FDA's December 16, 2021, response to the 2019 citizen petition." ECF No. 28 at 26.

This includes Plaintiffs' challenges to: (1) the 2000 Approval and FDA's 2016 Response to the 2002 Petition challenging that approval; (2) the 2019 Generic Approval; and (3), the April 2021 letter. As for FDA's December 2021 Response to the 2019 Petition, Defendants maintain review is limited to the narrow issues presented in the 2019 Petition — which did not include arguments concerning the Comstock Act. *Id.* at 27–28. ¹⁵ The Court disagrees with each of these arguments.

1. FDA "Reopened" its Decision in 2016 and 2021

FDA's final decision on a citizen petition constitutes "final agency action" under the APA. 21 C.F.R. § 10.45(c). Challenges to agency actions have a six-year statute of limitations period. *See* 28 U.S.C. § 2401(a). Therefore, the statute of limitations for challenging the 2000 Approval began running on March 29, 2016 — the date of FDA's denial of the 2002 Petition. Because the 2016 Denial of the 2002 Petition occurred more than six years before Plaintiffs filed this suit, Defendants argue the challenge is untimely. ECF No. 28 at 26. But if "the agency opened the issue up anew, and then reexamined and reaffirmed its prior decision," the agency's second action — rather than the original decision — starts the limitations period. *See Texas v. Biden*, 20 F.4th 928, 951 (5th Cir. 2021), *rev'd in part on other grounds*, 142 S. Ct. 2528 (2022).

The reopening doctrine arises "where an agency conducts a rulemaking or adopts a policy on an issue at one time, and then in a later rulemaking restates the policy or otherwise addresses the issue again without altering the original decision." Wash. All. of Tech. Workers v. U.S. Dep't of Homeland Sec., 892 F.3d 332, 345 (D.C. Cir. 2018); see also Nat'l Biodiesel Bd. v. EPA, 843 F.3d 1010, 1017 (D.C. Cir. 2016) ("The reopener doctrine allows an otherwise untimely challenge

¹⁵ The Court refers to the 2000 Approval, the 2016 Changes and denial of the 2002 Petition, and the 2019 Generic Approval collectively as FDA's "Pre-2021 Actions." Similarly, the Court refers to FDA's April 2021 letter and December 2021 Response as FDA's "2021 Actions."

¹⁶ Courts have even applied the doctrine where agencies decide *not* to engage in rulemaking and then revisit and reaffirm that decision. *See Pub. Citizen v. Nuclear Regul. Comm'n*, 901 F.2d 147, 152 (D.C. Cir. 1990).

to proceed where an agency has — either explicitly or implicitly — undertaken to reexamine its former choice.") (internal marks omitted); *CTIA-Wireless Ass'n v. F.C.C.*, 466 F.3d 105, 112 (D.C. Cir. 2006) (agency "reconsidered" policy by reaffirming policy and offering "two new justifications" not found in prior orders).

In the rulemaking context, courts have identified four non-exhaustive factors to apply the doctrine where the agency: (1) proposed to make some change in the rules or policies; (2) called for comment on new or changed provisions, but at the same time; (3) explained the unchanged, republished portions; and (4) responded to at least one comment aimed at the previously decided issue. *Tripoli Rocketry Ass'n, Inc. v. U.S. Bureau of Alcohol, Tobacco & Firearms*, No. 00CV0273(RBW), 2002 WL 33253171, at *6 (D.D.C. June 24, 2002) (internal marks omitted). But a court "cannot stop there" — it "must look to the entire context of the rulemaking including all relevant proposals and reactions of the agency to determine whether an issue was in fact reopened." *Pub. Citizen*, 901 F.2d at 150. For example, an agency can reopen a prior action if it removes restrictions or safeguards related to the first action or affects a "sea change" in the regulatory scheme. *See Sierra Club v. EPA*, 551 F.3d 1019, 1025 (D.C. Cir. 2008); *Nat'l Biodiesel*, 843 F.3d at 1017 (declining to apply doctrine when "the basic regulatory scheme remain[ed] unchanged"); *Pub. Citizen*, 901 F.2d at 152 (agency reopens decision when it reiterates a policy in such a way as to render the policy "subject to renewed challenge on any substantive grounds").

In the adjudication context, an agency need not solicit or respond to comments to reopen a decision because adjudication does not require notice and comment procedures. *See* 5 U.S.C. §§ 553(c), 554. The reopening doctrine has been applied in the adjudication context where an agency undertakes a "serious, substantive reconsideration" of "a prior administrative decision." *Chenault v. McHugh*, 968 F. Supp. 2d 268, 275 (D.D.C. 2013); *see also Battle v. Sec'y U.S. Dep't*

of Navy, 757 Fed. Appx. 172, 175 (3d Cir. 2018) (a petition for reconsideration can restart Section 2401(a)'s limitation period if the agency reopens the action based on a finding of "new evidence" or that the petition reflects some "changed circumstances"); *Peavey v. United States*, 128 F. Supp. 3d 85, 100 (D.D.C. 2015), *aff'd*, No. 15-5290, 2016 WL 4098768 (D.C. Cir. 2016) (reopening in 2011 occurred where agency "elected to conduct a substantive review" of servicemember's 1968 application to correct military records). For formal agency adjudications, even an order stating "only that it is denying reconsideration" is not conclusive if the agency has "altered its original decision." *Sendra Corp. v. Magaw*, 111 F.3d 162, 167 (D.C. Cir. 1997).

The standard for reopening is satisfied here. FDA's requirements for distribution in its 2000 Approval originally included:

- In-person dispensing from the doctor to the patient;
- Secure shipping procedures;
- Tracking system ability;
- Use of authorized distributors and agents; and
- Provision of the drug through direct, confidential physician distribution systems that ensures only qualified physicians will receive the drug for patient dispensing.

See ECF No. 1 at 40. FDA's 2016 Changes to this regulatory scheme included the following alterations:

- Extending the maximum gestational age at which a woman or girl can abort her unborn child from 49 days to 70 days;
- Altering the mifepristone dosage from 600 mg to 200 mg, the misoprostol dosage from 400 mcg to 800 mcg, and misoprostol administration from oral to buccal;
- Eliminating the requirement that administration of misoprostol occur in-clinic;
- Broadening the window for misoprostol administration to include a range of 24–48 hours after taking mifepristone, instead of 48 hours afterward;

- Adding a repeat 800 mcg buccal dose of misoprostol in the event of incomplete chemical abortion;
- Removing the requirement for an in-person follow-up examination after an abortion;
- Allowing "healthcare providers" other than physicians to dispense and administer the chemical abortion drugs; and
- Eliminating the requirement for prescribers to report all non-fatal serious adverse events from chemical abortion drugs.

Id. at 53–54. And in 2021, FDA removed the "in-person dispensing requirement" and signaled that it will soon allow pharmacies to dispense chemical abortion drugs. *Id.* at 68. Plaintiffs warn that without this requirement, "there is a dramatically reduced chance that the prescriber can confirm pregnancy and gestational age, discover ectopic pregnancies, and identify a victim of abuse or human trafficking being coerced into having a chemical abortion." ECF No. 120 at 19.

FDA's 2016 and 2021 Changes thus significantly departed from the agency's original approval of the abortion regimen. FDA repeatedly altered its original decision by removing safeguards and changing the regulatory scheme for chemical abortion drugs. *Sierra Club*, 551 F.3d at 1025; *Nat'l Biodiesel*, 843 F.3d at 1017. Additionally, FDA's response to the 2019 Petition *explicitly* states FDA "undertook a *full review* of the Mifepristone REMS Program" in 2021. ECF No. 1-44 at 7 (emphasis added); ¹⁷ *see also Peavey*, 128 F. Supp. 3d at 100–02 (agency reopened decision by conducting "thorough review" of the merits, even where the order did not state it was a "reconsideration" and did not reference prior decision). And FDA even granted the 2019 Petition in part. ECF No. 1-44 at 3. A "full review" of a REMS for a drug with known serious risks necessarily considers the possibility that a drug is too dangerous to be on the market, any mitigation

¹⁷ See also Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, FDA (Jan. 4, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (describing the 2021 review as "comprehensive").

strategy notwithstanding. FDA has the authority to withdraw an approved drug application on this basis. *See* 21 U.S.C. § 355(e). Because the agency reaffirmed its prior actions after undertaking a substantive reconsideration of those actions, the limitations period for those actions starts in 2021. *See Pub. Citizen*, 901 F.2d at 152 (an agency reconsidering and reaffirming original policy "necessarily raises the lawfulness of the original policy, for agencies have an everpresent duty to insure that their actions are lawful"). ¹⁸

Alternatively, the Court finds Plaintiffs' claims are not time-barred under the equitable tolling doctrine. *See United States v. Patterson*, 211 F.3d 927, 931 (5th Cir. 2000) (courts "must be cautious not to apply the statute of limitations too harshly"); *P & V Enters. v. U.S. Army Corps of Engr's*, 466 F. Supp. 2d 134, 149 (D.D.C. 2006), *aff'd*, 516 F.3d 1021 (D.C. Cir. 2008) (a "rebuttable presumption of equitable tolling" applies to lawsuits governed by the six-year limitations period of Section 2401(a)); *Bornholdt v. Brady*, 869 F.2d 57, 64 (2d Cir. 1989) ("The existence of § 2401 as a catchall provision . . . does not necessarily mean that Congress intended the six-year period to be applied whenever a substantive statute does not specify a limitations period."). "[A] litigant is entitled to equitable tolling of a statute of limitations only if the litigant establishes two elements: (1) that he has been pursuing his rights diligently, and (2) that some extraordinary circumstance stood in his way and prevented timely filing." *Menominee Indian Tribe of Wis. v. United States*, 577 U.S. 250, 255 (2016) (internal marks omitted); *see also Holland v. Florida*, 560 U.S. 631, 650 (2010) ("The flexibility inherent in equitable procedure enables courts

¹⁸ To date, it is unclear whether the reopening doctrine has been applied in the precise context of FDA's approval of an NDA. However, much of the rationale courts have applied in both the rulemaking and adjudication context applies here. And the Court is unaware of any legal principle that would preclude the doctrine from being applied to these facts. Assuming *arguendo* Plaintiffs' allegations are true, a contrary holding would mean there is *no* judicial remedy to FDA's insistence on keeping an unsafe drug on the market, so long as enough time has passed.

to meet new situations that demand equitable intervention, and to accord all the relief necessary to correct particular injustices.") (cleaned up).

Equitable tolling is appropriate here in large part because of FDA's unreasonable delay in responding to Plaintiff's 2002 and 2019 Petitions. *See WildEarth Guardians v. U.S. Dep't of Just.*, 181 F. Supp. 3d 651, 670 (D. Ariz. 2015) (it is "grossly inappropriate" to apply a statute of limitations where the agency unreasonably delayed a claim because the agency "could immunize its allegedly unreasonable delay from judicial review simply by extending that delay for six years") (internal marks omitted). It took FDA 13 years, 7 months, and 9 days to respond to the 2002 Petition. FDA then moved the goalposts by substantially changing the regulatory scheme on the *same day* it issued its Response. And it took FDA 2 years, 8 months, and 17 days to respond to the 2019 Petition which challenged those changes. Thus, in the 20 years between the 2002 Petition and the filing of this suit, Plaintiffs were waiting on FDA for over 16 of those years. *See Hill Dermaceuticals, Inc. v. U.S. Food & Drug Admin.*, 524 F. Supp. 2d 5, 9 (D.D.C. 2007) ("Once citizen petitions are submitted, the FDA Commissioner is required to respond in one of three manners 'within 180 days of receipt of the petition.") (quoting 21 C.F.R. § 10.30(e)(2)).

Additionally, statutes of limitations "are primarily designed to assure fairness to defendants," and "to promote justice by preventing surprises through the revival of claims that have been allowed to slumber until evidence is lost, memories have faded, and witnesses have disappeared." *Clymore v. United States*, 217 F.3d 370, 376 (5th Cir. 2000), *as corrected on reh'g* (Aug. 24, 2000) (internal marks omitted). But it "has not been argued, and cannot seriously be, that the government was unfairly surprised" when Plaintiffs filed this suit. *Id.* Plaintiffs have been

¹⁹ Incidentally, the delayed FDA Response is extreme but not unprecedented. *See, e.g., Bayer HealthCare, LLC v. U.S. Food & Drug Admin.*, 942 F. Supp. 2d 17, 22 (D.D.C. 2013) (FDA had yet to respond to a 2006 petition when it approved a related ANDA in 2013).

reasonably diligent in pursuing their claims. *See, e.g.*, ECF No. 1-4 at 6 (after years of waiting for FDA to respond to the Petition, Plaintiff "called upon" FDA to issue a response in 2005 and again in 2015). And the public interest in this case militates toward resolving Plaintiffs' claims on the merits. Accordingly, Plaintiffs' challenges to FDA's Pre-2021 Actions concerning chemical abortion drugs are not time-barred.

2. FDA's April 2021 Decision on In-Person Dispensing Requirements is not "Committed to Agency Discretion by Law"

Defendants also argue any challenge to FDA's decision regarding the in-person dispensing requirement is foreclosed under *Heckler v. Chaney*, 470 U.S. 821, 832 (1985). ECF No. 28 at 30. In *Heckler*, the Supreme Court held that FDA's decision not to recommend civil or criminal enforcement action to prevent violations of the FFDCA was "committed to agency discretion by law." 470 U.S. at 837–38; *see also Texas v. Biden*, 20 F.4th at 982 ("In other words, a litigant may not waltz into court, point his finger, and demand an agency investigate (or sue, or otherwise enforce against) 'that person over there.'"). "[T]he Supreme Court and the Fifth Circuit have consistently read *Heckler* as sheltering one-off nonenforcement decisions rather than decisions to suspend entire statutes." *Texas v. Biden*, 20 F.4th at 983. The "committed to agency discretion by law" exception to judicial review is a "very narrow exception" that applies *only* where "statutes are drawn in such broad terms that in a given case there is no law to apply." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971), *overruled on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977).

That is not the case here. The Secretary has the authority to determine that drugs with "known serious risks" may be dispensed "only in certain health care settings, such as hospitals." *See* 21 U.S.C. § 355-1(f)(3)(C); *Gomperts v. Azar*, No. 1:19-CV-00345-DCN, 2020 WL 3963864, at *1 (D. Idaho July 13, 2020) ("[T]hese restrictions mandate that Mifeprex be dispensed only in

certain healthcare settings"). The statute also provides other "elements to assure safe use" of dangerous drugs. 21 U.S.C. § 355-1(f)(1), (3). The Secretary must publicly explain "how such elements will mitigate the observed safety risk." 21 U.S.C. § 355-1(f)(2). The Secretary must also consider whether the elements would "be unduly burdensome on patient access to the drug" and must "minimize the burden on the health care delivery system." *Id.* Additionally, the elements "shall include [one] or more goals to mitigate a specific serious risk listed in the labeling of the drug." 21 U.S.C. § 355-1(f)(3). And as the Court will later explain, federal law prohibits the mailing of chemical abortion drugs. Thus, unlike in *Heckler*, there *is* "law to apply" to FDA's decision. *See Texas v. Biden*, 20 F.4th at 982 ("[T]he executive *cannot* look at a statute, recognize that the statute is telling it to enforce the law in a particular way or against a particular entity, and tell Congress to pound sand."). And even if Defendants have significant discretion in how they administer Section 355-1, that does not mean *all* related actions are immune to judicial review under Section 701(a)(2) of the APA.

In sum, Defendants cannot shield their decisions from judicial review merely by characterizing the challenged action as exercising "enforcement discretion." ECF No. 28 at 15; *see also Texas v. Biden*, 20 F.4th at 987 ("The Government is still engaged in enforcement — even if it chooses to do so in a way that ignores the statute. That's obviously not nonenforcement."); *id.* at 985 ("*Heckler* cannot apply to agency actions that qualify as rules under 5 U.S.C. § 551(4)."); *Heckler*, 470 U.S. at 833 n.4 (a decision to consciously and expressly adopt a general policy that is "so extreme as to amount to *abdication* of its statutory responsibilities" is not "committed to agency discretion") (emphasis added). Furthermore, the suggestion that FDA has full discretion

²⁰ See also Frequently Asked Questions (FAQS) about REMS, FDA (Jan. 26, 2018), https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems ("A REMS is required to ensure the drug is administered only in a health care facility with personnel trained to manage severe allergic reactions and immediate access to necessary treatments and equipment to managing such events.").

under Section 355-1 to not require *any* REMS for dangerous drugs would likely present nondelegation problems even under a modest view of that doctrine. *See, e.g., Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019). So too the notion that FDA could exercise its non-enforcement discretion in violation of other federal laws. Therefore, FDA's decision to not enforce the in-person dispensing requirement is reviewable because the decision is not committed to agency discretion by law.

3. Plaintiffs' Failure to Exhaust Certain Claims is Excusable

Plaintiffs allege FDA's 2021 Decision to dispense mifepristone through the mail did not acknowledge or address federal criminal laws that "expressly prohibit[] such downstream distribution." ECF No. 7 at 26. Defendants maintain Plaintiffs' argument is unexhausted because they failed to present it at any stage of any administrative proceeding. ECF No. 28 at 38. Similarly, Plaintiffs have not exhausted their challenge to FDA's approval of the supplemental NDA for generic mifepristone. *Id.* at 26. These failures to exhaust claims do not preclude judicial review.

"The general rule of nonreviewability is not absolute." *Myron v. Martin*, 670 F.2d 49, 52 (5th Cir. 1982). To begin, exhaustion is not required where the agency action is "in excess of" the agency's authority. *Id.* And a court will review for the first time "a particular challenge to an agency's decision which was not raised during the agency proceedings" where the agency action is "likely to result in individual injustice" or is "contrary to an important public policy extending beyond the rights of the individual litigants." *Id.*; *see also Mathews v. Eldridge*, 424 U.S. 319, 330 (1976) ("[C]ases may arise where a claimant's interest in having a particular issue resolved promptly is so great that deference to the agency's judgment is inappropriate."); *Abbott Laboratories v. Gardner*, 387 U.S. 136, 149 (1967) (injunctive remedies applied to administrative determinations should evaluate "both the fitness of the issues for judicial decision and the hardship

to the parties of withholding court consideration"); *Dawson Farms, LLC v. Farm Serv. Agency*, 504 F.3d 592, 606 (5th Cir. 2007) (exhaustion may be excused when "irreparable injury will result absent immediate judicial review"); *Bd. of Pub. Instruction of Taylor Cnty., Fla. v. Finch*, 414 F.2d 1068, 1072 (5th Cir. 1969) (exceptional circumstances include "where injustice might otherwise result").

Courts have also excused a claimant's failure to exhaust administrative remedies where exhaustion "would be futile because the administrative agency will clearly reject the claim." *Gulf Restoration Network v. Salazar*, 683 F.3d 158, 176 (5th Cir. 2012) (internal marks omitted); see also Oregon Nat. Desert Ass'n v. McDaniel, 751 F. Supp. 2d 1151, 1159 (D. Or. 2011) (exceptional circumstances include evidence of administrative bias). Additionally, courts will consider any issue that was "raised with sufficient clarity to allow the decision maker to understand and rule on the issue raised, whether the issue was considered sua sponte by the agency or was raised by someone other than the petitioning party." *Pac. Choice Seafood Co. v. Ross*, 976 F.3d 932, 942 (9th Cir. 2020). In short, "there is no bright-line standard as to when this requirement has been met." *Nat'l Parks & Conservation Ass'n v. Bureau of Land Mgmt.*, 606 F.3d 1058, 1065 (9th Cir. 2010). Finally, "[a]dministrative remedies that are inadequate need not be exhausted." *Coit Indep. Joint Venture v. Fed. Sav. & Loan Ins. Corp.*, 489 U.S. 561, 587 (1989) (a lack of reasonable time limits in the claims procedure renders the procedure inadequate).

a. Contrary to Public Policy

Judicial review of Plaintiffs' unexhausted claims is appropriate for several reasons. First, Defendants' alleged violation of the Comstock Act would be "contrary to an important public policy." *Myron*, 670 F.2d at 52. As a case Defendants rely upon explains, the word "abortion" in the statute "indicates a national policy of discountenancing abortion as inimical to the national

life." *See Bours*, 229 F. at 964; ECF No. 28-1 at 206. And twenty-two states filed an amicus brief arguing FDA's decision to permit mail-in chemical abortion harms the public interest by undermining states' ability to enforce laws regulating abortion. ²¹ ECF No. 100 at 17.

b. Individual Injustice and Irreparable Injury

Second, the agency's actions are "likely to result in individual injustice" or cause "irreparable injury." *Myron*, 670 F.2d at 52; *Dawson*, 504 F.3d at 606. Plaintiffs allege "many intense side effects" and "significant complications requiring medical attention" resulting from Defendants' actions. ²² ECF No. 7 at 13. Many women also experience intense psychological trauma and post-traumatic stress from excessive bleeding and from seeing the remains of their aborted children. *See* ECF No. 96 at 25–29; Pauline Slade et al., *Termination of pregnancy: Patient's perception of care*, J. of FAMILY PLANNING & REPRODUCTIVE HEALTH CARE Vol. 27, No. 2, 72–77 (2001) ("Seeing the foetus, in general, appears to be a difficult aspect of the medical termination process which can be distressing, bring home the reality of the event and may influence later emotional adaptation."). Parenthetically, said "individual justice" and "irreparable injury" analysis also arguably applies to the unborn humans extinguished by mifepristone — especially in

²¹ See David S. Cohen et al., Abortion Pills, 76 STAN. L. REV. 1, 9 (forthcoming 2024) ("Despite state laws, mailed medication abortion can cross borders in ways that undermine state laws... A new organization, Mayday Health, for example, focuses on those who live in states with abortion bans, giving users step-by-step instructions on how to set up temporary addresses in an abortion permissive state and forward the mail into the banned state.") (internal marks omitted).

²² At least 4,213 adverse events from chemical abortion drugs have been reported. *See* ECF No. 96 at 12 n.16. But the actual number is likely far higher because non-fatal adverse events are no longer required to be reported, and because more than 60 percent of women and girls' emergency room visits after chemical abortions are miscoded as miscarriages. *See* James Studnicki et al., *A Post Hoc Exploratory Analysis: Induced Complications Mistaken for Miscarriage in the Emergency Room are a Risk Factor for Hospitalization*, 9 HEALTH SERV. RSCH. MGMT. EPIDEMIOLOGY 1, 1 (2022); *see also* ECF No. 1-8 at 7 (describing Plaintiffs' difficulty in submitting adverse event reports to mifepristone manufacturer Danco). Other data sources such as the Center for Disease Control and Prevention Abortion Surveillance Reports are "profoundly flawed" because state reporting "is voluntary, with many states reporting intermittently and some not at all." Studnicki et al., *supra* note 9, at 2. One Plaintiff physician alleges that when she reported an adverse event to her state's health department, the "report was rejected because the State said it was not a 'true' adverse event because the patient ultimately recovered." ECF No. 1-10 at 7.

the post-*Dobbs* era. *See Dobbs*, 142 S. Ct. at 2261 ("Nothing in the Constitution or in our Nation's legal traditions authorizes the Court to adopt [the] theory of life" that States are *required* "to regard a fetus as lacking even the most basic human right — to live — at least until an arbitrary point in a pregnancy has passed.") (internal marks omitted); Brief of *Amici Curiae* Scholars of Jurisprudence John M. Finnis and Robert P. George in Support of Petitioners, *Dobbs*, 142 S. Ct. 2228 (2022) (arguing unborn humans are constitutional "persons" entitled to equal protection).

c. Administrative Procedures are Inadequate

Third, FDA's combined response time of over sixteen years to Plaintiffs' two petitions shows their procedures have been inadequate. *See Coit*, 489 U.S. at 587; *Bowen v. City of New York*, 476 U.S. 467, 476 (1986) ("[T]he harm imposed by exhaustion would be irreparable."). FDA slow-walked — or rather, *snail*-walked — its response to the 2002 Petition by waiting nearly *fourteen years* to deny the petition. ECF No. 7 at 9. Requiring Plaintiffs to exhaust their administrative remedies may equate to another decade-plus of waiting for the agency to give them the time of day.

d. Exhaustion would be Futile

Alternatively, any attempt by Plaintiffs to challenge Defendants' actions would likely be futile. Even if Plaintiffs did not endure sixteen years of delay, dawdle, and dithering, their efforts would surely "be futile because the administrative agency will clearly reject the claim." *Gulf Restoration Network*, 683 F.3d at 176. "President Biden has emphasized the need to protect access to mifepristone" since the day of the Supreme Court's decision in *Dobbs*. ²³ President Biden stated that "protecting reproductive rights is essential to our Nation's health, safety, and

²³ See FACT SHEET: President Biden to Sign Memorandum on Ensuring Safe Access to Medication Abortion, THE WHITE HOUSE (Jan. 22, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/01/22/fact-sheet-president-biden-to-sign-presidential-memorandum-on-ensuring-safe-access-to-medication-abortion/.

progress."²⁴ He also criticized States' efforts to impose restrictions on mifepristone because such efforts "have stoked confusion, sowed fear, and may prevent patients from accessing safe and effective FDA-approved medication."²⁵ Thus, it is unlikely FDA would reverse course on its "mail-order" abortion regimen. ECF No. 7 at 7. Defendants' position on the Comstock Act in this litigation only confirms that fact. *See* ECF No. 28 at 38 ("Plaintiffs misconstrue the Comstock Act.").²⁶

e. The Comstock Act was raised with Sufficient Clarity

Finally, the Comstock Act issue was "raised with sufficient clarity." *Ross*, 976 F.3d at 942. This is because: (1) the 2019 Petition requested FDA to retain the in-person requirement for dispensing of chemical abortion drugs; and (2) the Comstock Act issue was also raised by the United States Postal Service and the Department of Health & Human Services on July 1, 2022, "[i]n the wake of" *Dobbs*. ²⁷ The Office of Legal Counsel specifically mentioned FDA's regimen for chemical abortion drugs when concluding "the mere mailing of such drugs to a particular jurisdiction is an insufficient basis for concluding that the sender intends them to be used unlawfully." OLC Memo at *1. This shows not only that the issue was raised with sufficient clarity, but also the *futility* of raising the issue before the agency. Therefore, Plaintiffs' failure to exhaust their claims does not preclude judicial review.

²⁴ Memorandum on Further Efforts to Protect Access to Reproductive Healthcare Services, THE WHITE HOUSE (Jan. 22, 2023), https://www.whitehouse.gov/briefing-room/presidential-actions/2023/01/22/memorandum-on-further-efforts-to-protect-access-to-reproductive-healthcare-services/.

²⁵ *Id*.

²⁶ The D.C. Circuit has hinted that the futility doctrine is ordinarily predicated on the "worthlessness of an argument before an agency that *has rejected it* in the *past*" rather than the likelihood that "the agency *would reject it* in the *future*." *Tesoro Refin. & Mktg. Co. v. FERC*, 552 F.3d 868, 874 (D.C. Cir. 2009). But in this case, there is no principled distinction between the two scenarios. Defendants do not even pretend the agency might have accepted Plaintiffs' arguments. Other cases may involve uncertainty about *future* agency rejection, but it is not this case.

²⁷ See Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions, 2022 WL 18273906 (O.L.C. Dec. 23, 2022) ("OLC Memo").

C. Plaintiffs' Challenges to FDA's 2021 Actions Have a Substantial Likelihood of Success on the Merits

"To satisfy the first element of likelihood of success on the merits," Plaintiffs "must present a prima facie case but need not show that [they are] certain to win." *Janvey v. Alguire*, 647 F.3d 585, 595–96 (5th Cir. 2011) (internal marks omitted). Under the APA, courts must "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A) & (C).

The Court will first address FDA's 2021 Actions that eliminated the in-person dispensing requirement and announced that FDA would allow abortionists to dispense chemical abortion drugs by mail or mail-order pharmacy. Plaintiffs have a substantial likelihood of success on their claims that these actions violate federal law.

1. The Comstock Act prohibits the Mailing of Chemical Abortion Drugs

The Comstock Act declares "[e]very obscene, lewd, lascivious, indecent, filthy or vile article, matter, thing, device, or substance" to be "nonmailable matter" that "shall not be conveyed in the mails or delivered from any post office or by any letter carrier." 18 U.S.C. § 1461. The next clauses declare nonmailable "[e]very article or thing designed, adapted, or intended for producing abortion, or for any indecent or immoral use; and [e]very article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion, or for any indecent or immoral purpose." *Id.* Similarly, Section 1462 forbids the use of "any express company or other common carrier" to transport chemical abortion drugs "in interstate or foreign commerce."

Defendants' argument that the Comstock Act does not prohibit the mailing of chemical abortion drugs relies on the "reenactment canon." That is, courts may distill a statute's meaning

when "federal courts of appeals settled upon a consensus view" and "Congress never modified the relevant statutory text to reject or displace this settled construction." ECF No. 28 at 39. This purported "consensus view" is that the Comstock Act does not prohibit the mailing of items designed to produce abortions "where the sender does not intend them to be used unlawfully." *Id.* This argument is unpersuasive for several reasons.

"Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change." *Lorillard v. Pons*, 434 U.S. 575, 580 (1978). But "[t]here is an obvious trump to the reenactment argument": "[w]here the law is plain, subsequent reenactment does not constitute an adoption of a previous administrative construction." *Brown v. Gardner*, 513 U.S. 115, 121 (1994) (quoting *Demarest v. Manspeaker*, 498 U.S. 184, 190 (1991)); *see also Milner v. Dep't of Navy*, 562 U.S. 562, 576 (2011) ("[W]e have no warrant to ignore clear statutory language on the ground that other courts have done so."). Additionally, the presumption only applies when the judicial or administrative gloss "represented settled law when Congress reenacted the [language in question]." *Keene Corp. v. United States*, 508 U.S. 200, 212 (1993); *see also Jama v. Immigr. & Customs Enf't*, 543 U.S. 335, 349 (2005) (presumption applies only when the supposed judicial consensus at the time of reenactment was "so broad and unquestioned that we must presume Congress knew of and endorsed it"); *Davis v. United States*, 495 U.S. 472, 482 (1990); *Fed. Deposit Ins. Corp. v. Phila. Gear Corp.*, 476 U.S. 426, 437 (1986); *United States v. Powell*, 379 U.S. 48, 55 n.13 (1964).²⁸

²⁸ See also Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 325 (2012) ("But how numerous must the lower-court opinions be, or how prominent and long-standing the administrative interpretation, to justify the level of lawyerly reliance that justifies the canon? What about two intermediate-court decisions? (We doubt it — though some cases have relied on just a single intermediate-court decision.) Or seven courts of first instance? (Perhaps.)").

The canon is easily overcome for one simple reason: it is a dubious means of ascertaining congressional intent. "There are plenty of reasons to reenact a statute that have nothing to do with codifying the glosses that courts have already put on the statute." CALEB NELSON, STATUTORY INTERPRETATION 481 (2011). For example, perhaps the original statute contained a "sunset" provision. Maybe Congress wanted to change the statute in some other respects but found it easier to communicate those changes by reenacting a modified version of the complete statute "than by casting each discrete change as an amendment to the existing language." Id. at n.14. Or Congress was perhaps conducting "a more general codification or reorganization of the statutes in a particular field, for the sake of making the structure of its statutes easier to follow." Id. "Or maybe Congress simply wanted to enact the relevant title of the United States Code into positive law." *Id.* "To the extent that Congress reenacts statutory language for one of those other reasons, members of Congress may well not mean to be expressing any view at all about the glosses that have piled up in the meantime." Id.; see also HENRY M. HART, JR., & ALBERT M. SACKS, THE LEGAL PROCESS: BASIC PROBLEMS IN THE MAKING AND APPLICATION OF LAW 1367 (William N. Eskridge, Jr., & Philip P. Frickey eds., 1994) (tent. ed. 1958) (criticizing the canon for adding to the costs of the legislative process in counterproductive ways).

Here, the plain text of the Comstock Act controls. *See Bostock v. Clayton Cnty.*, *Ga.*, 140 S. Ct. 1731, 1749 (2020) ("[W]hen the meaning of the statute's terms is plain, our job is at an end."); *Lawson v. FMR LLC*, 571 U.S. 429, 441 (2014) ("Absent any textual qualification, we presume the operative language means what it appears to mean."). The Comstock Act declares "nonmailable" every "article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use it or apply it for producing *abortion*." 18 U.S.C. § 1461 (emphasis added). It is indisputable that chemical abortion drugs are both

"drug[s]" and are "for producing abortion." Therefore, federal criminal law declares they are "nonmailable." *See Texas v. Becerra*, No. 5:22-CV-185-H, 2022 WL 3639525, at *26 n.21 (N.D. Tex. Aug. 23, 2022) ("[F]ederal law bar[s] the importation or delivery of any device or medicine designed to produce an abortion.").

The statute plainly does *not* require intent on the part of the seller that the drugs be used "unlawfully." To be sure, the statute does contain a catch-all provision that prohibits the mailing of such things "for producing abortion, *or for any indecent or immoral purpose*." 18 U.S.C. § 1461 (emphasis added). But "or" is "almost always disjunctive." *Encino Motorcars, LLC v. Navarro*, 138 S. Ct. 1134, 1141 (2018) (internal marks omitted). Additionally, the "or" in Section 1461 is preceded by a comma, further disjoining the list of nonmailable matter. Thus, the Court does not read the "or" as an "and." Similarly, the Act requires that the defendant "knowingly uses the mails for the mailing" of anything declared by the Act "to be nonmailable." 18 U.S.C. § 1461. A defendant could satisfy this *mens rea* requirement by mailing mifepristone and knowing it is for producing abortion. The statute does not require anything more. *See, e.g., United States v. Lamott*, 831 F.3d 1153, 1157 (9th Cir. 2016) (where Congress "intends to legislate a specific intent crime," the statute typically uses the phrase "with the intent to") (internal marks omitted).

Even if the statute were ambiguous, the legislative history also supports this interpretation. ²⁹ See H.R. Rep. No. 91-1105, at 2 (1970) ("Existing statutes completely prohibit the importation, interstate transportation, and mailing of contraceptive materials, or the mailing of advertisement or information concerning how or where such contraceptives may be obtained or how conception may be prevented."). Congress unsuccessfully tried to modify Section 1461 to

²⁹ This Court reviews the legislative history as mere evidence of the ordinary public meaning of the current statutory language. *See* ANTONIN SCALIA, A MATTER OF INTERPRETATION 17 (1997) ("It is the *law* that governs, not the intent of the lawgiver . . . Men may intend what they will; but it is only the laws that they enact which bind us.").

prohibit mailing drugs "intended by the offender . . . to be used to produce an *illegal* abortion." *See* REP. OF THE SUBCOMM. ON CRIM. JUST., 95TH CONG., REP. ON RECODIFICATION OF FED. CRIM. LAW 40 (Comm. Print 1978) (emphasis added); *Bostock*, 140 S. Ct. at 1824 (Kavanaugh, J., dissenting) ("In the face of the unsuccessful legislative efforts . . . judges may not rewrite the law simply because of their own policy views."). In fact, the House Subcommittee Report on the proposed amendment acknowledged the plain meaning of the statute: "[U]nder current law, the offender commits an offense whenever he 'knowingly' mails any of the designated abortion materials," and the proposed amendment would "require proof that the offender *specifically intended* that the mailed materials be used to produce an illegal abortion." If Congress believed the statute *already* contained the "intentionality" requirement gloss in prior reenactments, there is little reason why Congress would amend the provision to *include* that requirement.

Defendants aver Plaintiffs' interpretation of the Comstock Act is foreclosed by the Food and Drug Administration Amendments Act of 2007 ("FDAAA") for one reason: "Congress was well aware that it was directing mifepristone's preexisting distribution scheme to continue" in enacting the FDAAA. ECF No. 28 at 40. But neither "critics [of FDA's 2000 Approval of mifepristone] nor anyone else in the congressional debate mentioned the Comstock Act." OLC Memo at *7 n.18; *see also In re Lively*, 717 F.3d 406, 410 (5th Cir. 2013) ("Repeals by implication are disfavored and will not be presumed unless the legislature's intent is 'clear and manifest.'") (internal marks omitted). Because the Comstock Act is not even implicitly mentioned

³⁰ *Bostock*'s majority opinion warns that "speculation about why a later Congress declined to adopt new legislation offers a 'particularly dangerous' basis on which to rest an interpretation of an existing law a different and earlier Congress did adopt." 140 S. Ct. at 1747. But the opinion does not suggest judges can "rewrite the law." Instead, *Bostock*'s stated rationale was that the disputed term was implicit in the statutory text all along. No such "textualist" analysis could plausibly justify Defendants' interpretation of the Comstock Act, and Defendants offer none.

³¹ REP. OF THE SUBCOMM. ON CRIM. JUST., 95TH CONG., REP. ON RECODIFICATION OF FED. CRIM. LAW 40 (Comm. Print 1978) (emphasis added).

in the FDAAA's enactment, there is no repeal by implication. And in any case, Defendants' arguments based on legislative history cannot overcome clear statutory text.

Consequently, reenactment of the Comstock Act does not constitute an adoption of prior constructions because "the law is plain." *Brown*, 513 U.S. at 121 (1994). Even if that were not the case, the reenactment canon does not apply here because the relevant judicial glosses do not represent a "broad and unquestioned" consensus. *Jama*, 543 U.S. at 349. Defendants rely heavily on the OLC Memo that purports to establish this "consensus." But none of the cases cited in the OLC Memo support the view that the Comstock Act bars the mailing of abortion drugs only when the sender has the specific intent that the drugs be used unlawfully.

On the contrary, the Seventh Circuit reasoned that the word "abortion" in the context of the Act indicates "a national policy of discountenancing abortion as inimical to the national life." *Bours*, 229 F. at 964. *Bours* further declared "it is immaterial what the local statutory definition of abortion is, what acts of abortion are included, or what excluded." *Id.* Similarly, the Sixth Circuit's decision in *Davis v. United States* only suggests that legitimate uses of drugs should not fall within the scope of the statute "merely because they are capable of illegal uses." 62 F.2d 473, 474 (6th Cir. 1933). In other words, the *Davis* holding reflects the position that *legitimate* uses — uses beyond the purposes the statute condemns — should be excluded from the scope of the statute, *not* that whatever uses are *lawful under state law* should be. ECF No. 114 at 10. Likewise, the Second Circuit interpreted the statute to embrace articles the 1873 Congress "would have denounced as immoral if it had understood all the conditions under which they were to be used." *United States v. One Package*, 86 F.2d 737, 739 (2d Cir. 1936). The court further observed that "[t]he word 'unlawful' would make this clear as to articles for producing abortion." *Id.*; *see also* James S. Witherspoon, *Reexamining Roe: Nineteenth-Century Abortion Statutes and the Fourteenth*

Amendment, 17 St. Mary's L.J. 29, 33 (1985) (explaining that thirty of thirty-seven states had statutory abortion prohibitions in 1868 — just five years before Congress enacted the Comstock Act).

Defendants maintain "the legality of the agency actions needs to be judged at the time of the decision, all of which occurred when *Roe* and *Casey* were still good law." ECF No. 136 at 109. Even assuming that is true in all cases, *Roe* did not prohibit *all* restrictions on abortions. And it is not obvious that enforcement of the Comstock Act post-*Casey* would have necessarily run afoul of *Casey*'s "arbitrary 'undue burden' test." *Dobbs*, 142 S. Ct. at 2266. Therefore, there is no reason why the Act should not have at least been considered. In any case, the Comstock Act plainly forecloses mail-order abortion in the present, and Defendants have stated no present or future intention of complying with the law. Defendants cannot immunize the illegality of their actions by pointing to a small window in the past where those actions might have been legal.

In sum, the reenactment canon is inapplicable here because the law is plain. Even if that were not true, the cases relied on in the OLC Memo do not support Defendants' interpretation. And even if they did, a small handful of cases cannot constitute the "broad and unquestioned" consensus required under the reenactment canon. Therefore, Plaintiffs have a substantial likelihood of prevailing on their claim that Defendants' decision to allow the dispensing of chemical abortion drugs through mail violates unambiguous federal criminal law.

2. FDA's 2021 Actions violate the Administrative Procedure Act

Because FDA's 2021 Actions violate the Comstock Act, they are "otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Additionally, the actions were likely "arbitrary and capricious." *Id.* FDA relied on FDA Adverse Event Reporting System data despite the agency's 2016 decision to eliminate the requirement for abortionists to report non-fatal "adverse events."

ECF No. 7 at 25. Defendants maintain that "Plaintiffs offer no explanation for why it was impermissible to rely on the reported data." ECF No. 28 at 33. The explanation should be obvious — it is circular and self-serving to practically eliminate an "adverse event" reporting requirement and then point to a low number of "adverse events" as a justification for removing even *more* restrictions than were already omitted in 2000 and 2016. In other words, it is a predetermined conclusion in search of non-data — a database designed to produce a null set. But even if FDA's explanation were well-reasoned, the actions would still run afoul of the Comstock Act and therefore violate the APA.

D. Plaintiffs' Challenges to FDA's Pre-2021 Actions Have a Substantial Likelihood of Success on the Merits

1. FDA's 2000 Approval violated Subpart H

In 1992, FDA issued regulations "needed to assure safe use" of *new* drugs designed to treat life-threatening diseases like HIV and cancer. *See* 57 Fed. Reg. 58,942, 58,958 (Dec. 11, 1992) (codified at 21 C.F.R. § 314.520). Subpart H — titled "Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses" — applies to drugs that satisfy two requirements. First, the drug must have been "studied for [its] safety and effectiveness in treating serious or life-threatening illnesses." 21 C.F.R. § 314.500. And second, the drug must "provide [a] meaningful therapeutic benefit to patients over existing treatments." *Id.* "These rules were promulgated by FDA . . . as part of an attempt to correct perceived deficiencies in FDA's approval process made apparent by the need to quickly develop drugs for HIV/AIDS patients." ECF No. 1-13 at 20.

"When FDA originally approved Mifeprex, the agency relied upon Subpart H to place certain restrictions on the manufacturer's distribution of the drug product to assure its safe use." ECF No. 28 at 14; *see also* ECF No. 1-13 at 9 (the American Medical Association explained that "[Mifepristone] poses a severe risk to patients unless the drug is administered as part of a complete

treatment plan under the supervision of a physician"). Thus, to satisfy Subpart H, FDA deemed pregnancy a "serious or life-threatening illness[]" and concluded that mifepristone "provide[d] [a] meaningful therapeutic benefit to patients over existing treatments." *See* 21 C.F.R. §§ 314.500; 314.560. FDA was wrong on both counts.

a. Pregnancy is not an "Illness"

Pregnancy is a normal physiological state most women experience one or more times during their childbearing years — a natural process essential to perpetuating human life. Defendants even admit pregnancy is not an "illness." FDA claims the Final Rule explained Subpart H was available for serious or life-threatening "conditions," whether or not they were understood colloquially to be "illnesses." ECF No. 28 at 36. But the Final Rule says no such thing. "One comment asserted that neither depression nor psychosis is a disease, nor is either one serious or life-threatening." 57 Fed. Reg. 58,946. FDA responded to the comment that "signs of these diseases are readily studied" and that its reference to depression and psychosis "was intended to give examples of conditions or diseases that can be serious for certain populations or in some or all of their phases." *Id.* In other words, FDA's response to this comment was *not* that depression and psychosis qualify because they are "conditions" even though they are not colloquially understood as "illnesses." Rather, FDA simply disagreed with the comment's characterization of these conditions and explained that they *were* examples of "diseases" that can be "serious." Nothing in the Final Rule supports the interpretation that pregnancy is a serious or life-threatening illness.

FDA's 2016 Denial of the 2002 Petition is similarly unpersuasive. For example, FDA noted that approximately fifty percent of pregnancies in the United States are unintended and that unintended pregnancies may cause depression and anxiety. ECF No. 1-28 at 5. But categorizing

complications or negative psychological experiences arising *from* pregnancy as "illnesses" is materially different than classifying pregnancy *itself* as a serious or life-threatening illness *per se*. Tellingly, FDA never explains how or why a "condition" would *not* qualify as a "serious or life-threatening illness." Suppose that a woman experiences depression because of lower back pain that inhibits her mobility. Under FDA's reading, a new drug used to treat lower back pain — which can cause depression, just like unplanned pregnancy — could obtain accelerated approval under Subpart H.

Defendants cite zero cases reading Subpart H like FDA reads Subpart H. On the contrary, courts have read "serious or life-threatening illnesses" to mean what it says. *See, e.g., Tummino v. Hamburg*, 936 F. Supp. 2d 162, 182 (E.D.N.Y. 2013) ("Whether an illness is 'serious or life-threatening' 'is based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.") (quoting 57 Fed. Reg. at 13235). The preamble to the final rule also clarified the terms "would be used as FDA has defined them in the past." 57 Fed. Reg. at 13235.

Likewise, the Final Rule expressly stated this nomenclature "is the same as FDA defined and used the terms" in two rulemakings: the first in 1987; the second in 1988. 57 Fed. Reg. at 58,945. In the 1988 rulemaking, FDA defined "life-threatening" to include *diseases or conditions* "where the likelihood of death is high unless the course of the disease is interrupted (*e.g.*, AIDS and cancer), as well as diseases or conditions with potentially fatal outcomes where the end point of clinical trial analysis is survival (*e.g.*, increased survival in persons who have had a stroke or heart attack)." *See* 53 Fed. Reg. at 41517; *id.* at 41516 (referencing "AIDS, cancer, Parkinson's disease, and other serious conditions"); *CSX Transp., Inc. v. Ala. Dep't of Revenue*, 562 U.S. 277, 294 (2011) (the canon of *ejusdem generis* "limits general terms that follow specific ones to matters

similar to those specified") (internal marks omitted). Therefore, "diseases" and "conditions" are used interchangeably, and even "conditions" must be "serious" or "life-threatening" as defined.

Food and Drug scholars have understood Subpart H's scope the same way. See, e.g., Charles Steenburg, The Food and Drug Administration's Use of Postmarketing (Phase IV) Study Requirements: Exception to the Rule?, 61 FOOD & DRUG L.J. 295, 323 (2006) (Subpart H "extend[s] only to drugs and biological products that target[] 'serious or life-threatening illnesses' and offer[] a 'meaningful' benefit over existing treatments"). Even the Population Council argued to FDA that "the imposition of Subpart H is unlawful" because "[t]he plain meaning of these terms does not comprehend normal, everyday occurrences such as pregnancy and unwanted pregnancy." ECF No. 1-14 at 21. This reading is also consistent with the fact that aside from mifepristone, FDA had approved fewer than forty NDAs under Subpart H by early 2002. See id. at 20. And of those other approvals, twenty were for the treatment of HIV and HIV-related diseases, nine were for the treatment of various cancers and their symptoms, four were for severe bacterial infections, one was for chronic hypertension, and one was for leprosy. Id. "One of these things is not like the others, one of these things just doesn't belong." See Sesame Street.

b. Defendants are not entitled to Auer Deference

Courts sometimes extend *Auer* deference "to agencies' reasonable readings of genuinely ambiguous regulations." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2408 (2019). *Auer* deference is rooted in an "always rebuttable" presumption "that Congress would generally want the agency to play the primary role in resolving regulatory ambiguities." *Id.* at 2412. "*Auer* deference is sometimes appropriate and sometimes not." *Id.* at 2408. "First and foremost, a court should not afford *Auer* deference unless the regulation is genuinely ambiguous." *Id.* at 2415. "And before concluding that a rule is genuinely ambiguous, a court must exhaust all the traditional tools of construction." *Id.*

(internal marks omitted). "That means a court cannot wave the ambiguity flag just because it found the regulation impenetrable on first read." *Id.* If genuine ambiguity remains, the agency's reading must still be "reasonable." *Id.* And even if the regulation is genuinely ambiguous, the agency's interpretation "must in some way implicate its substantive expertise." *Id.* at 2417. Finally, an agency's reading of a rule must reflect "fair and considered judgment" to receive *Auer* deference. *Id.* (internal marks omitted).

Here, *Auer* deference is not appropriate because "the language of [the] regulation is plain and unambiguous." *McCann v. Unum Provident*, 907 F.3d 130, 144 (3d Cir. 2018). As explained, FDA's definitions in prior rulemakings foreclose its interpretation of Subpart H. If there is any ambiguity in "serious or life-threatening illnesses," the ordinary meaning principle resolves that ambiguity. *See Bostock*, 140 S. Ct. at 1825 (Kavanaugh, J, dissenting) ("The ordinary meaning principle is longstanding and well settled."). "[C]ommon parlance matters in assessing the ordinary meaning" of a statute or regulation "because courts heed how most people would have understood the text." *Id.* at 1828 (internal marks omitted). The word "illness" refers to "poor health; sickness," or "a specific sickness or disease, or an instance of such." Merriam-Webster invokes the definition for "sickness" — "an unhealthy condition of body or mind." Likewise, a Wikipedia search for "illness" re-directs to the entry for "Disease," which is defined as "a particular *abnormal* condition that negatively affects the structure or function of all or part of an organism, and that is not immediately due to any external injury." Pregnancy, on the other

³² *Illness*, Dictionary.com, https://www.dictionary.com/browse/illness (last visited Mar. 22, 2023); *see also Bostock*,140 S. Ct. at 1766 (Alito, J, dissenting) ("Dictionary definitions are valuable because they are evidence of what people at the time of a statute's enactment would have understood its words to mean.").

³³ Illness, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/illness (last visited Mar. 22, 2023).

³⁴ *Disease*, Wikipedia, https://en.wikipedia.org/wiki/Disease (emphasis added) (last visited Mar. 22, 2023).

hand, is defined as "the time during which one or more offspring develops (gestates) inside a woman's uterus (womb)."³⁵

Most readers would not define pregnancy to be a serious or life-threatening illness. Even FDA does not earnestly defend that position. True, complications can arise during pregnancy, and said complications *can* be serious or life-threatening. But that does not make pregnancy *itself* an illness. *See* ECF No 1-13 at 21. And even if the regulation were genuinely ambiguous after exhausting all traditional tools of statutory construction, Defendants' interpretation: (1) is *not* reasonable; (2) does not implicate their substantive expertise; and (3) does not reflect fair and considered judgment. Accordingly, Defendants are not entitled to *Auer* deference on their interpretations of "serious or life-threatening illnesses." By interpreting Subpart H's scope as reaching any state or side effect that can be considered an undefined "condition," Defendants broaden the regulation on accelerated approval of new drugs farther than the text of the regulation would ever suggest. Therefore, FDA's approval of chemical abortion drugs under Subpart H exceeded its authority under the regulation's first requirement.

c. Chemical Abortion Drugs do not provide a "Meaningful Therapeutic Benefit"

FDA also exceeded its authority under the second requirement of Subpart H. In addition to treating a serious or life-threatening illness, chemical abortion drugs must also provide a "meaningful therapeutic benefit" to patients over surgical abortion. 21 C.F.R. § 314.500. As explained, this cannot be the case because chemical abortion drugs do not treat "serious or life-threatening illnesses" — a prerequisite to reaching the second requirement. *Id.* Similarly, chemical abortion drugs cannot be "therapeutic" because the word relates to the treatment or curing of disease. ³⁶ But even putting that aside, chemical abortion drugs do not provide a meaningful

³⁵ Pregnancy, Wikipedia, https://en.wikipedia.org/wiki/Pregnancy (last visited Mar. 22, 2023).

³⁶ Therapeutic, Dictionary.com, https://www.dictionary.com/browse/illness (last visited Mar. 28, 2023).

therapeutic benefit over surgical abortion. *See* 21 C.F.R. § 314.500 (examples include where the benefit is the "ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy"). To the extent surgical abortion can be considered a "therapy," the clinical trials did not compare chemical abortion with surgical abortion to find such a benefit. ECF No. 1 at 44.

Defendants argue just one "meaningful therapeutic benefit": chemical abortion drugs avoided "an invasive surgical procedure and anesthesia in 92 percent of" patients in the trial. ECF No. 28 at 37. But "[b]y defining the 'therapeutic benefit' solely as the avoidance of the current standard of care's delivery mechanism, FDA effectively guarantees that a drug will satisfy this second prong of Subpart H as long as it represents a different method of therapy." ECF No. 1-14 at 22. And even if that *were* a benefit, chemical abortions are over fifty percent more likely than surgical abortion to result in an emergency room visit within thirty days. ECF No. 7 at 21.³⁷ Consequently, the number of chemical abortion-related emergency room visits increased by over *five hundred percent* between 2002 and 2015. ECF No. 1 at 19.

One study revealed the overall incidence of adverse events is "fourfold higher" in chemical abortions when compared to surgical abortions.³⁸ Women who underwent chemical abortions also experienced far higher rates of hemorrhaging, incomplete abortion, and unplanned surgical evacuation.³⁹ Chemical abortion patients "reported significantly higher levels of pain, nausea,

³⁷ Some studies report that the exact number is *fifty-three* percent. *See* Studnicki et al., *supra* note 22.

³⁸ See Maarit Niinimäki et al., *Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 114 OBSTETRICS & GYNECOLOGY 795 (2009). FDA agrees with this study but finds it "not surprising" given that chemical abortion "is associated with longer uterine bleeding." ECF No. 1-44 at 38. *See also* ECF No 1-13 at 15, n.68–72 (collecting studies demonstrating the far higher rates of adverse events in chemical abortion over surgical abortion).

³⁹ *Id*.

vomiting and diarrhea during the actual abortion than did surgical patients . . . Post-abortion pain occurred in 77.1% of mifepristone patients compared with only 10.5% of surgical patients." ECF No 1-13 at 24. And before the approval, an FDA medical officer recognized the "medical regimen had *more* adverse events, particularly bleeding, than did surgical abortion. Failure rates exceeded those for surgical abortion . . . This is a serious potential disadvantage of the medical method." *Id.* at 23 (emphasis added).

Other studies show eighty-three percent of women report that chemical abortion "changed" them — and seventy-seven percent of those women reported a *negative* change. 40 Thirty-eight percent of women reported issues with anxiety, depression, drug abuse, and suicidal thoughts because of the chemical abortion. 41 Bleeding from a chemical abortion, unlike surgical abortion, can last up to several weeks. 42 And the mother seeing the aborted human "appears to be a difficult aspect of the medical termination process which can be distressing, bring home the reality of the event and may influence later emotional adaptation." 43 "For example, one woman was surprised and saddened to see that her aborted baby 'had a head, hands, and legs' with '[d]efined fingers and toes." ECF No. 1 at 21. The entire abortion process takes place within the mother's home, without physician oversight, potentially leading to undetected ectopic pregnancies, failure of rH factor incompatibility detection, and misdiagnosis of gestational age — all leading to severe or even fatal

⁴⁰ See Katherine A. Rafferty & Tessa Longbons, #AbortionChangesYou: A Case Study to Understand the Communicative Tensions in Women's Medication Abortion Narratives, 36 HEALTH COMM. 1485, 1485–94 (2021), https://www.tandfonline.com/doi/full/10.1080/10410236.2020.1770507.

⁴¹ *Id*.

⁴² After Mifepristone: When bleeding will start and how long will it last?, WOMEN ON WEB, https://www.womenonweb.org/en/page/484/when-will-you-start-bleeding-and-howlong-will-it-last. See also ECF No. 1-28 at 25 ("Up to 8% of all subjects may experience some type of bleeding for 30 days or more.").

⁴³ Pauline Slade et al., *Termination of Pregnancy: Patient's Perception of Care*, 27 J. OF FAMILY PLANNING & REPRODUCTIVE HEALTH CARE 72, 76 (2001).

consequences. *See* ECF No. 96 at 15–17. Contrary to popular belief and talking points, the evidence shows chemical abortion is *not* "as easy as taking Advil." *Id.* at 20.

Compelling evidence suggests the statistics provided by FDA on the adverse effects of chemical abortion *understate* the negative impact the chemical abortion regimen has on women and girls. When women seek emergency care after receiving the chemical abortion pills, the abortionist that prescribed the drugs is usually *not* the provider to manage the mother's complications. ⁴⁴ Consequently, the treating physician may not know the adverse event is due to mifepristone. *Id.* at 13. Studies support this conclusion by finding *over sixty percent* of women and girls' emergency room visits after chemical abortions are miscoded as "miscarriages" rather than adverse effects to mifepristone. ⁴⁵ Simply put, FDA's data are incomplete and potentially misleading, as are the statistics touted by mifepristone advocates.

Lastly, chemical abortion does not "treat patients unresponsive to, or intolerant of, available therapy." *See* 21 C.F.R. § 314.500. "To the contrary, because 'medical abortion failures should be managed with surgical termination' the option for surgical abortion must be available for any Mifeprex patient." ECF No. 1-14 at 23 (quoting the Mifeprex "Warnings" label). One study showed that 18.3 percent of women required surgical intervention after the chemical abortion regimen failed. *Id.* Hence, "any patient who would be intolerant of surgical abortion, if such a class of patients exists, cannot use the Mifeprex Regimen." *Id.* at 24. On balance, the data reflect little to no benefit over surgical abortion — much less a "meaningful therapeutic" benefit.

⁴⁴ Kathi Aultman et al., *Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019*, 36 ISSUES IN LAW & MED., 3–26 (2021).

⁴⁵ Studnicki et al., *supra* note 9.

d. Defendants' Misapplication of Subpart H has not been Cured by Congress

Defendants contend "Plaintiffs' arguments about Subpart H have been overtaken by congressional action." ECF No. 28 at 35. In the FDAAA, "Congress specifically directed" that drugs with elements to assure safe use "in effect on the effective date on this Act" would be "deemed to have in effect an approved" REMS. *Id.* (citing Pub. L. No. 110-85, § 909(b)(1)). But the sponsors of such drugs were also required to submit a proposed REMS within 180 days. *See* Pub. L. No. 110-85, § 909(b)(3). Hence, Congress "deemed" preexisting safety requirements to be a sufficient REMS until a *new* REMS was approved. The FDAAA did not affect, however, whether an NDA was properly approved or authorized under Subpart H in the first place. Rather, the FDAAA required that such drugs needed continued restrictions in place to mitigate risks. Implementation of a REMS under the FDAAA does not somehow repeal or supplant the approval process under Subpart H or 21 U.S.C. § 355(d). The FDAAA only eased the regulatory transition from Subpart H to the REMS provision. Simply stated, Congress's *general* reiteration that dangerous drugs should carry a REMS did not codify FDA's *specific* approval of the mifepristone NDA. It did not consider the chemical abortion approval at all.

In sum, Subpart H doubly forecloses FDA's approval of mifepristone. *At most*, FDA might have lawfully approved mifepristone under Subpart H for cases where a pregnant woman's life or health is in danger. But even a limited approval of this sort would still not render pregnancy an "illness." And surgical abortion — a statistically far safer procedure — would still be available to her. But in any case, that is not what FDA did. Instead, FDA manipulated and misconstrued the text of Subpart H to greenlight elective chemical abortions on a wide scale. Therefore, Plaintiffs have a substantial likelihood of prevailing on their claim that Defendants violated Subpart H.

2. FDA's Pre-2021 Actions were Arbitrary and Capricious

Under the FFDCA, a pharmaceutical company seeking to market a new drug must first obtain FDA approval via an NDA. *See* 21 U.S.C. § 355(a), (b). The NDA must include "adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d). The trials must "provide an adequate basis for physician labeling." 21 C.F.R. § 312.21(c). In those trials, "the drug is used *the way it would be administered when marketed*." The Secretary must deny the NDA if "he has insufficient information to determine whether such drug is safe for use under such conditions." 21 U.S.C. § 355(d)(4).

Here, the U.S. trials FDA relied upon when approving mifepristone required that: (1) each woman receive an ultrasound to confirm gestational age and exclude an ectopic pregnancy; ⁴⁷ (2) physicians have experience in performing surgical abortions and admitting privileges at medical facilities that provide emergency care; (3) all patients be within one hour of emergency facilities or the facilities of the principal investigator; and (4) women be monitored for four hours to check for adverse events after taking misoprostol. ECF No. 7 at 23. However, FDA included *none* of these requirements — which were explicitly stated in the clinical trial FDA relied on most — in the 2000 Approval. *Id.* Likewise, FDA's 2016 Changes omitted the requirements of the underlying tests: (1) gestational age confirmed by ultrasounds; (2) participants required to return for clinical assessment; and (3) surgical intervention if necessary. *Id.* at 24.

⁴⁶ *Glossary*, WEILL CORNELL MEDICINE, https://research.weill.cornell.edu/compliance/human-subjects-research/institutional-review-board/glossary-faqs-medical-terms-lay-3 (last visited Mar. 22, 2023) (emphasis added).

⁴⁷ The 2016 Denial of the 2002 Petition briefly notes the two French clinical trials did not *require* an ultrasound but instead left the decision to the investigator's discretion. ECF No. 1-28 at 19 n.47. Defendants do not explain how many investigators chose to perform an ultrasound. The higher that number is, the more it supports Plaintiffs' argument. But in any case, the U.S. trial was larger than the two French trials combined and is therefore the more reliable study. *Id.* at 9.

Defendants maintain "there is no legal basis for Plaintiffs' contention that the approved conditions of use of a drug must duplicate the protocol requirements for the clinical trials supporting its approval." ECF No. 28 at 35. But FDA's actions must not be arbitrary and capricious. ⁴⁸ See 5 U.S.C. § 706(2)(A); United States v. An Article of Device . . . Diapulse, 768 F.2d 826, 832-33 (7th Cir. 1985) (concluding FDA's denial was not arbitrary and capricious because the proposed labeling did not "specify conditions of use that are similar to those followed in the studies"). "The scope of review under the arbitrary and capricious standard is narrow and a court is not to substitute its judgment for that of the agency." Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (internal marks omitted). "Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." Id. (internal marks omitted); see also Sw. Elec. Power Co. v. EPA, 920 F.3d 999, 1013 (5th Cir. 2019) (judicial review of agency action "is not toothless"). Courts must "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Id. (internal marks omitted). An agency's action is "arbitrary and capricious" if it "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.* Defendants fail this test.

⁴⁸ Plaintiffs also frame what the Court characterized as the "study-match problem" as a statutory violation of the FFDCA. *See* ECF No. 7 at 22. The Court does not read 21 U.S.C. § 355(d) as necessarily *requiring* an exact "match" between trial conditions and the conditions on the approved labeling of a new drug. But Section 355(d) does mandate the Secretary "issue an order refusing to approve the application" if he finds the investigations do not show the drug is safe for use under the suggested conditions in the proposed labeling. FDA made such a finding yet did not deny the Application. *See* ECF No. 1-24 at 6 ("We have concluded that adequate information has not been presented to demonstrate that the drug, when marketed in accordance with the terms of distribution proposed, is safe and effective for use as recommended."). Thus, even if Defendants could survive "arbitrary and capricious" analysis of the "study-match problem," Defendants still violated Section 355(d) on their own terms.

a. The 2000 Approval

To begin, FDA "entirely failed to consider an important aspect of the problem" by omitting any evaluation of the psychological effects of the drug or an evaluation of the long-term medical consequences of the drug. *State Farm*, 463 U.S. at 43; ECF No. 84 at 12. Considering the intense psychological trauma and post-traumatic stress women often experience from chemical abortion, this failure should not be overlooked or understated. Nor was the drug tested for under-18 girls undergoing reproductive development. ⁴⁹ But that is not all. Clinical trial protocols in the United States for the 2000 Approval required a transvaginal ultrasound for each patient to accurately date pregnancies and identify ectopic pregnancies. ECF No. 1-28 at 19. But FDA ultimately concluded that "a provider can accurately make such a determination by performing a pelvic examination and obtaining a careful history." *Id.* Thus, FDA determined it was inappropriate "to mandate how providers clinically assess women for duration of pregnancy and for ectopic pregnancy." ECF No. 1-28 at 19. FDA believed "it is reasonable to expect that the women's providers would not have prescribed Mifeprex if a pelvic ultrasound examination had clearly identified an ectopic pregnancy." *Id.* at 20.

FDA thus assumes physicians will ascertain gestational age. But put another way, there is simply *no requirement* that *any* procedure is done to rule out an ectopic pregnancy — which *is* a serious and life-threatening situation. This is arbitrary and capricious. The mere fact that other clinical methods can be used to date pregnancies does not support the view that it should be the

⁴⁹ In 1998, FDA issued the "Pediatric Rule," which "mandated that drug manufacturers evaluate the safety and effectiveness of their products on pediatric patients, absent an applicable exception." *Ass'n of Am. Physicians & Surgeons, Inc. v. U.S. Food & Drug Admin.*, 391 F. Supp. 2d 171, 173–74 (D.D.C. 2005). Two years after approving mifepristone, FDA was enjoined from enforcing the Pediatric Rule because it lacked statutory authority in issuing the rule. *See Ass'n of Am. Physicians & Surgeons v. FDA*, 226 F. Supp. 2d 204, 222 (D.D.C. 2002). In response, Congress enacted the Pediatric Research Equity Act of 2003 to codify the Pediatric Rule. *See* 21 U.S.C. § 355c. In the 2000 Approval, FDA clarified that the Mifeprex NDA was covered by the Pediatric Rule. *See* ECF No. 1-26 at 4. However, FDA fully waived the rule's requirements without explanation. ECF No. 1-28 at 30.

provider's decision to decide which method — if any — is used to make this determination. FDA has never denied that an ultrasound is the *most accurate* method to determine gestational age and identify ectopic pregnancies. *See* ECF No. 1-14 at 62. And the fact that other clinical methods can be used does not mean that all such methods are equal in their accuracy and reliability. ⁵⁰ FDA did rely on a study showing that clinicians rarely underestimate gestational age. ECF No. 1-28 at 19 n.49. But this study does nothing to support FDA's view that a transvaginal ultrasound is not necessary to diagnose ectopic pregnancies. To this point, FDA merely argues that even transvaginal ultrasounds do not *guarantee* an existing ectopic pregnancy will be identified. *Id.* at 19. If that is the case, it does not follow that it should be left to the provider's discretion to employ less reliable methods — or no methods at all.

Correct diagnosis of gestational age and ectopic pregnancies is vital. The error in FDA's judgment is borne out by myriad stories and studies brought to the Court's attention. One woman alleged she did not receive an ultrasound or any other physical examination before receiving chemical abortion drugs from Planned Parenthood. ECF No. 1 at 22. "The abortionist misdated the baby's gestational age as six weeks, resulting in the at-home delivery of a 'lifeless, fully-formed baby in the toilet,' later determined to be around 30-36 weeks old." Id.; see also Patel v. State, 60 N.E.3d 1041, 1043 (Ind. Ct. App. 2016) (woman who used chemical abortion drugs "delivered a live baby of approximately twenty-five to thirty weeks gestation who died shortly after birth"). Another woman was given chemical abortion drugs during an ectopic pregnancy because her ultrasound "was not even that of a uterus but was of a bladder." ECF No. 31 at 5.

⁵⁰ Studies reflect that women recurrently miscalculate their unborn child's gestational age. See P. Taipale & V. Hiilesmaa, Predicting delivery date by ultrasound and last menstrual period in early gestation, 97 OBSTETRICS GYN. 189 (2001); David A. Savitz et al., Comparison of pregnancy dating by last menstrual period, ultrasound scanning, and their combination, 187 AM. J. OBSTETRICS GYN. 1660 (2002).

⁵¹ This incident also demonstrates that even where ultrasounds are used, only a qualified provider can assure they are done properly.

The resulting rupture "led to massive infection and a collapse of her vital systems." *Id.* Amicus Human Coalition identified four of their clients who were unknowingly ectopic when they arrived at their clinic "with abortion pills in hand." ECF No. 96 at 20. And at least two women died from chemical abortion drugs last year. *See* ECF No. 120 at 30 n.5. One of those women was an estimated twenty-one weeks pregnant. *See id.* Presumably, the fact that the woman obtained chemical abortion drugs more than two months past FDA's gestational age cutoff suggests that no adequate procedures confirmed the gestational age in her case.

FDA has also reported at least ninety-seven cases where women with ectopic pregnancies took mifepristone. ⁵² But these data are likely incomplete because FDA now only requires reporting on deaths. *See* ECF No. 1 at 4. And as noted above, hospitals often miscode complications from chemical abortions as miscarriages. Studies show that women are thirty percent more likely to die from a ruptured ectopic pregnancy while seeking abortions if the condition remains undiagnosed. ⁵³ A woman may interpret the warning signs of an ectopic pregnancy — cramping and severe bleeding — as side effects of mifepristone. In reality, the symptoms indicate her life is in danger. ⁵⁴ Another study revealed that of 5,619 chemical abortion visits, 452 patients had a pregnancy of "unknown location" and 31 were treated for ectopic pregnancy — including 4 that were ruptured. ⁵⁵ Yet another study examined 3,197 unique, U.S.-only adverse event reports dated September 2000

⁵² FDA, *Mifepristone US. Post-Marketing Adverse Events Summary Through 6/30/2022*, http://www.fda.gov/media/164331/download.

⁵³ H.K. Atrash et al., *Ectopic pregnancy concurrent with induced abortion: incidence and mortality*, 162 Am. J. OBSTETRICS GYN. 726 (1990).

⁵⁴ *Id*.

⁵⁵ Alisa B. Goldberg et al., *Mifepristone and Misoprostol for Undesired Pregnancy of Unknown Location*, 139 OBSTETRICS GYN. 771, 775 (2022).

to February 2019.⁵⁶ That study noted 20 deaths, 529 life-threatening events, and 1,957 *severe* adverse events before concluding that a pre-abortion ultrasound "should be required to rule out ectopic pregnancy and confirm gestational age."⁵⁷

The record confirms FDA once shared these concerns. After all, many tragedies could be avoided by auditing physician qualifications and requiring ultrasounds. In 1996, the FDA Advisory Committee expressed to the Population Council "serious reservations" on how the drugs were described "in terms of assuring safe and adequate credentialing of providers." ECF No. 1-14 at 51. Population Council initially committed to conducting post-approval studies in 1996, and FDA reiterated these requirements mere months before the September 2000 approval. *See* ECF No. 1-24 at 6 ("We remind you of your commitments dated September 16, 1996, to perform the . . . Phase 4 studies."). Those protocols would have required, *inter alia*, that the Population Council: (1) assess the long-term effects of multiple uses of mifepristone; (2) ascertain the frequency with which women follow the regimen and outcomes of those that do not; (3) study the safety and efficacy of chemical abortion in girls under the age of eighteen; and (4) ascertain the regimen's effects on children born after treatment failure. ⁵⁸ ECF No. 1-28 at 32.

⁵⁶ Aultman et al., *supra* note 44.

⁵⁷ Id

⁵⁸ See 153 Cong. Rec. S5765 (daily ed. May 9, 2007) (statement of Sen. Coburn) ("I recently learned of a woman who was given RU-486 after she had a seizure. Her physicians assumed that the seizure was life-threatening to the baby she was carrying and gave her RU-486 for a therapeutic abortion. RU-486 was not effective in her case and the woman carried the baby to term. When the baby was born at a low birth weight, it also suffered from failure to thrive. That baby has had three subsequent brain surgeries due to hydrocephalus. The baby also suffers from [idiopathic lymphocytic colitis] — an inflammatory disease of the colon, which is extremely rare in children. It is clear that RU-486 not only is unsafe in women, but it is also not completely effective. And when it is not effective, the results are devastating.").

Similarly, on February 18, 2000 — months before chemical abortion approval — FDA informed the Population Council that "adequate information ha[d] *not* been presented to demonstrate that the drug, when marketed in accordance with the terms of distribution proposed, is safe and effective for use as recommended." ECF No. 1-24 at 6 (emphasis added). FDA then stated the "restrictions on distribution will need to be amended." *Id.* Accordingly, FDA informed the Population Council that it would proceed under Subpart H — the *only* provision that could implement the requisite restrictions on distribution. *Id.* But as explained above, that was the improper regulation for the approval of chemical abortion. Regardless, the restrictions were insufficient to ensure safe use.

On June 1, 2000, FDA privately delivered to the Population Council a set of proposed restrictions to rectify the safety issues. Said proposal required physicians who were: (1) "trained and authorized by law" to perform surgical abortions; (2) trained in administering mifepristone and treating adverse events; and (3) allowed "continuing access (*e.g.*, admitting privileges) to a medical facility equipped for instrumental pregnancy termination, resuscitation procedures, and blood transfusion at the facility or [one hour's] drive from the treatment facility." *See* ECF No. 1-14 at 53–54. When FDA's proposal was leaked to the press, a political and editorial backlash ensued. ⁵⁹ In response, the Population Council rejected the proposal and repudiated the restrictions the sponsor *itself* proposed in 1996 — what FDA deemed a "very significant change" in the sponsor's position. *Id.* at 50. Because "[t]he whole idea of mifepristone was to increase access," abortion advocates argued that restrictions on mifepristone "would effectively eliminate" the drug's "main advantage" and would "kill[] the drug." ⁶⁰

⁵⁹ Sheryl Gay Stolberg, *FDA Adds Hurdles in Approval of Abortion Pill*, THE NEW YORK TIMES (June 8, 2000), https://www.nytimes.com/2000/06/08/us/fda-adds-hurdles-in-approval-of-abortion-pill.html.

⁶⁰ *Id*.

In September 2000, FDA abandoned its safety proposals and acquiesced to the objections of the Population Council and Danco. Despite its "serious reservations" about mifepristone's safety, FDA approved a regimen that relied on a self-certification that a prescribing physician has the *ability* to diagnose ectopic pregnancies. *Id.* at 51, 62; *see also* ECF No. 1-28 at 21 ("[W]e concluded that there was no need for special certification programs or additional restrictions."). FDA later released the applicant *entirely* from its Phase 4 duties — *twelve years* after the 1996 commitment. ECF Nos. 1-24 at 6, 1-28 at 32; *see also* 21 C.F.R. § 314.510 ("Approval under this section will be subject to the requirement that the applicant study the drug further, to verify and describe its clinical benefit, where there is uncertainty . . . of the observed clinical benefit to ultimate outcome. Postmarketing studies would usually be studies *already underway*.") (emphasis added).

FDA *must* refuse to approve a drug if the agency determines there is "insufficient information to determine whether such drug is safe for use" or a "lack of substantial evidence that the drug will have the effect it purports or is represented to have" under the conditions of use in the proposed label. 21 U.S.C. § 355(d)(4)–(5); *see also* 21 C.F.R. § 314.125(b). FDA is therefore required to deny an NDA if it makes the exact findings FDA made in its 2000 review. "[A]n agency's decision to change course may be arbitrary and capricious if the agency ignores or countermands its earlier factual findings without reasoned explanation for doing so." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 537 (2009). The agency must ordinarily "display awareness that it *is* changing position," and "must show that there are good reasons for the new policy." *Id.* at 515. And "if the agency's decision was in any material way influenced by political concerns it should not be upheld." *Earth Island Inst. v. Hogarth*, 494 F.3d 757, 768 (9th Cir. 2007). FDA's only acknowledgments of its prior proposals were that "FDA and the applicant were not always in

full agreement about the distribution restrictions" and that fulfilling the Phase 4 commitments "would not be feasible." ECF No. 1-28 at 18, 32–33.

The Court does not second-guess FDA's decision-making lightly. But here, FDA acquiesced on its legitimate safety concerns — in violation of its statutory duty — based on plainly unsound reasoning and studies that did not support its conclusions. There is also evidence indicating FDA faced significant political pressure to forego its proposed safety precautions to better advance the *political* objective of increased "access" to chemical abortion — which was the "whole idea of mifepristone." As President Clinton's Secretary for Health & Human Services ("HHS") explained to the White House, it was *FDA* that arranged the meeting between the French pharmaceutical firm — who owned the mifepristone patent rights — and the eventual drug sponsor Population Council. The purpose of the FDA-organized meeting was "to facilitate an agreement between those parties to work together to test [mifepristone] and file a new drug application." ECF No. 95 at 14. HHS also "initiated" another meeting "to assess how the United States Government" — *i.e.*, the Clinton Administration — "might facilitate successful completion of the negotiations" between the French firm and the American drug sponsor to secure patent rights and eventual FDA approval. *Id.* at 16. In fact, for their "negotiations [to be] successfully concluded," the HHS Secretary believed American pressure on the French firm was necessary. ⁶² *Id.*

Whether FDA abandoned its proposed restrictions because of political pressure or not, one thing is clear: the lack of restrictions resulted in many deaths and many more severe or life-

⁶¹ Stolberg, *supra* note 59.

⁶² See also Lars Noah, A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics, 36 WAKE FOREST L. REV. 571, 576 (2001) ("The Clinton administration went to great lengths to bring mifepristone into the United States. From pressuring the hesitant manufacturer to apply for approval, and utilizing a specialized review procedure normally reserved for life-saving drugs, to imposing unusual restrictions on distribution, and promising to keep the identity of the manufacturer a secret, the FDA's approval process deviated from the norm in several respects.").

threatening adverse reactions. Due to FDA's lax reporting requirements, the exact number is not ascertainable. But it is likely far higher than its data indicate for reasons previously mentioned. Whatever the numbers are, they likely would be considerably lower had FDA not acquiesced to the pressure to increase access to chemical abortion at the expense of women's safety. FDA's failure to *insist* on the inclusion of its proposed safety restrictions was not "the product of reasoned decisionmaking." *State Farm*, 463 U.S. at 52. To hold otherwise would be "tantamount to abdicating the judiciary's responsibility under the [APA] to set aside agency actions that are 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995) (quoting 5 U.S.C. § 706(2)(A)). Finally, the 2000 Approval was also arbitrary and capricious because it violated Subpart H. 63

b. The 2016 Changes

FDA made numerous substantial changes to the chemical abortion regimen in 2016. These changes include but are not limited to: (1) eliminating the requirement for prescribers to report *all* nonfatal serious adverse events; (2) extending the maximum gestational age from 49 days to 70 days; (3) eliminating the requirement that administration of misoprostol occurs in-clinic; (4) removing the requirement for an in-person follow-up exam; and (5) allowing "healthcare providers" other than physicians to dispense chemical abortion drugs. ECF No. 1 at 53–54. Plaintiffs allege the 2016 Changes were also arbitrary and capricious "because *none* of the studies on which FDA relied were designed to evaluate the safety and effectiveness of chemical abortion

⁶³ As one scholar noted, "the agency took this route so that it could better justify imposing otherwise unauthorized restrictions on the use and distribution of the drug." *See* Noah, *supra* note 62, at 582. And "while agency action may generally be 'entitled to a presumption of regularity,' here FDA itself acknowledges that its action has not been regular: it failed to respond to the Citizen Petition for years." *Bayer*, 942 F. Supp. 2d at 25 (internal marks omitted). At the hearing, Defendants' leading argument for Subpart H was that "none of it really matters" because of the FDAAA. *See* ECF No. 136 at 100. "This is not the argument of an agency that is confident in the legality of its actions." ECF No. 100 at 15.

drugs for use under the conditions prescribed, recommended, or suggested in the proposed labeling." ECF No. 7 at 24.

For similar reasons as the 2000 Approval, the Court agrees. Unlike the crucial studies FDA relied upon to extend the maximum gestational age, change the dosing regimen, and authorize a repeat dose of misoprostol, the labeling approved by FDA in 2016 did *not* require: (1) an ultrasound; (2) an in-person follow-up exam; or (3) the ability of abortionists to personally perform a surgical abortion if necessary. *Id.* Simply put, FDA built on its already-suspect 2000 Approval by removing *even more* restrictions related to chemical abortion drugs that were present during the final phase of the investigation. And it did so by relying on studies that included the very conditions FDA refused to adopt. ⁶⁴ None of the studies compared the safety of the changes against the thencurrent regimen, nor under the labeled conditions of use. Moreover, FDA shirked any responsibility for the consequences of its actions by eliminating any requirement that non-fatal adverse events be reported. Thus, FDA took its chemical abortion regimen — which had already culminated in *thousands* of adverse events suffered by women and girls — and removed what little restrictions protected these women and girls, systematically ensuring that almost all new adverse events would go unreported or underreported.

Defendants aver that "Plaintiffs point to no statutory provision requiring the conditions of use in a drug's approved labeling to duplicate the protocol requirements used in the studies supporting its approval." ECF No. 28 at 32. "The [FFDCA] thus requires FDA to apply its scientific expertise in determining whether a drug has been shown to be safe and effective under particular conditions of use, and the application of that expertise is owed substantial deference."

Id. But FDA does not have unfettered discretion to approve dangerous drugs under substantially

⁶⁴ See ECF No. 1-35.

different conditions than the tests, trials, and studies cited. To be clear, the Court does not hold that *any* difference between approval conditions and testing conditions — no matter how well-justified — means the approval fails as a matter of law. But the agency "must cogently explain why it has exercised its discretion in a given manner," and that explanation must be "sufficient to enable [the Court] to conclude that the [agency's action] was the product of reasoned decisionmaking." *A.L. Pharma*, 62 F.3d at 1491 (quoting *State Farm*, 463 U.S. at 52). Defendants have not done so here. FDA's 2016 Actions were not the product of reasoned decision-making.

c. The 2019 Generic Approval

The FFDCA allows a generic drug manufacturer to submit an ANDA for premarket review and approval. 21 U.S.C. § 355(j); 21 C.F.R. § 314.94. The generic sponsor must show that: (1) the conditions of use prescribed, recommended, or suggested in the labeling have been previously approved; and (2) the drug product is chemically the same as the already approved drug — allowing it to rely on FDA's previous finding of safety and effectiveness for the approved drug. *Id.* On April 11, 2019, FDA approved GenBioPro, Inc.'s ANDA for a generic version of mifepristone. ECF No. 7 at 10. In doing so, FDA relied on Mifeprex's safety data. *Id.*

Plaintiffs argue the 2019 Approval was unlawful because FDA relied on the unlawful 2000 Approval and its unlawful 2016 Changes when approving generic mifepristone. ECF No. 7 at 27. If FDA withdraws the listed drug on which the ANDA-approved generic drug is based, the agency is generally required to withdraw the generic drug as well. 21 U.S.C. § 355(j)(6); 21 C.F.R. § 314.151. Because the Court agrees that Plaintiffs have a substantial likelihood of success in their challenges to the 2000 and 2016 Actions, the Court is inclined to agree with Plaintiffs on this claim as well.

E. There Is a Substantial Threat of Irreparable Harm

To satisfy the second element of the preliminary injunction standard, Plaintiffs "must demonstrate that if the district court denied the grant of a preliminary injunction, irreparable harm would result." *Janvey*, 647 F.3d at 600 (internal marks omitted). "In general, a harm is irreparable where there is no adequate remedy at law, such as monetary damages." *Id.* (internal marks omitted). "When determining whether injury is irreparable, it is not so much the magnitude but the irreparability that counts." *Texas v. U.S. Env't Prot. Agency*, 829 F.3d 405, 433–34 (5th Cir. 2016) (internal marks omitted). Where "the likelihood of success on the merits is very high, a much smaller quantum of injury will sustain an application for preliminary injunction." *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 131 (D.D.C. 1997), *aff'd*, 140 F.3d 1060 (D.C. Cir. 1998) (citing *Cuomo v. U.S. Nuclear Regul. Comm'n*, 772 F.2d 972, 974 (D.C.Cir. 1985) (per curiam)). Plaintiffs' Motion satisfies this standard.

For reasons already stated, Plaintiffs are likely to suffer irreparable harm if the Motion is not granted. At least two women died from chemical abortion drugs just last year. *See* ECF No. 120 at 30 n.5;⁶⁵ *Deerfield Med. Ctr. v. City of Deerfield Beach*, 661 F.2d 328, 338 (5th Cir. 1981) (finding irreparable harm to third-party pregnant women). "The physical and emotional trauma that chemical abortion inflicts on women and girls cannot be reversed or erased." ECF No. 7 at 28; *see also E.E.O.C. v. Chrysler Corp.*, 733 F.2d 1183, 1186 (6th Cir. 1984) (affirming irreparable harm for plaintiffs' "emotional distress"). "The crucial time that doctors need to treat these injured women and girls cannot be replaced." *Id.* "The mental and monetary costs to these doctors cannot be repaid." *Id.* "And the time, energy and resources that Plaintiff medical associations expend in

⁶⁵ One of those women was reportedly twenty-one weeks pregnant, which is well past the cutoff for gestational age even after the 2016 Changes. *See id.* The other maternal death occurred while the woman was seven weeks pregnant, which falls within FDA's current restrictions. *Id.*

response to FDA's actions on chemical abortion drugs cannot be recovered." *Id.*; *see also Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 485 F. Supp. 3d 1, 56 (D.D.C. 2020) (obstacles that make it more difficult for an organization to accomplish its mission provide injury for both standing *and* irreparable harm).

Defendants' respond that the drugs at issue have been on the market for more than twenty years. ECF No. 28 at 41. This argument ignores that many restrictions and safeguards — which no longer exist — were in place for most of that time. Defendants also argue "Plaintiffs' extreme delay" in filing suit shows they face no irreparable harm. *Id.* at 42. But the time between the allegedly unlawful actions and the filing of a suit "is not determinative" of whether relief should be granted. *Boire v. Pilot Freight Carriers, Inc.*, 515 F.2d 1185, 1193 (5th Cir. 1975). Here, eleven months does not constitute an "extreme" delay. *See, e.g., Optimus Steel, LLC v. U.S. Army Corps of Eng'rs*, 492 F. Supp. 3d 701, 720 (E.D. Tex. 2020) (eleven-month delay did not militate against equitable relief because "the Court can presume that Plaintiff needed ample time to evaluate its claims"). 66 "[T]emporary injunctive relief may still be of great value to protect against ongoing harms, even if the initial harm is in the distant past." *N.L.R.B. v. Hartman & Tyner, Inc.*, 714 F.3d 1244, 1252 (11th Cir. 2013).

The Court also disagrees that Plaintiffs' theories of injury "are too speculative to even show standing." ECF No. 28 at 42. Plaintiffs have credibly alleged past and future harm resulting from the removal of restrictions for chemical abortion drugs. "Although a court's analysis of likelihood of success in the context of an injunctive relief request is governed by the deferential APA's arbitrary and capricious standard, a court does not always owe deference to federal agencies' positions concerning irreparable harm, balance of hardships, or public interest." San Luis & Delta-

⁶⁶ To clarify, the eleven months referenced here is the approximate time between FDA's "final agency action" in the December 2021 Denial of the 2019 Petition and the commencement of this case.

Mendota Water Auth. v. Jewell, 969 F. Supp. 2d 1211, 1215 (E.D. Cal. 2013); see also R.J. Reynolds Vapor Co. v. FDA, No. 23-60037 (5th Cir. Mar. 23, 2023)⁶⁷ (noting FDA's public interest argument was "obviously colored by the FDA's view of the merits"); Sierra Forest Legacy v. Sherman, 646 F.3d 1161, 1186 (9th Cir. 2011) ("If the federal government's experts were always entitled to deference concerning the equities of an injunction, substantive relief against federal government policies would be nearly unattainable, as government experts will likely attest that the public interest favors the federal government's preferred policy.").

F. Preliminary Injunction Would Serve the Public Interest

The third and fourth factors — assessing the harm to the opposing party and weighing the public interest — "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). "[T]he public interest weighs strongly in favor of preventing unsafe drugs from entering the market." *Hill Dermaceuticals*, 524 F. Supp. 2d at 12. "[T]here is generally no public interest in the perpetuation of unlawful agency action." *State v. Biden*, 10 F.4th 538, 560 (5th Cir. 2021) (internal marks omitted). And "there is a strong public interest in meticulous compliance with the law by public officials." *Fund for Animals, Inc. v. Espy*, 814 F. Supp. 142, 152 (D.D.C. 1993); *see also State v. Biden*, 10 F.4th at 559. "Indeed, the Constitution itself declares a prime public interest that the President and, by necessary inference, his appointees in the Executive Branch 'take Care that the Laws be faithfully executed." *Id.* (internal marks omitted). Additionally, Defendants' actions harm States' efforts to regulate chemical abortion "in the interests of life, health, and liberty." ECF No. 100 at 21. "The Court appreciates FDA's institutional interest but, given its long-standing disregard of [Plaintiffs'] Citizen Petition[s], its argument has a hollow center." *Bayer HealthCare*, 942 F. Supp. 2d at 26. To the extent Defendants

⁶⁷ https://www.ca5.uscourts.gov/opinions/pub/23/23-60037-CV0.pdf.

and third parties would be harmed by an injunction, the Court still balances these factors in favor of ensuring that women and girls are protected from unnecessary harm and that Defendants do not disregard federal law.

For these reasons, a preliminary injunction would serve the public interest. Defendants maintain that unaborted children of the women "who seek but are unable to obtain an abortion" are "expected to do worse in school," "to have more behavioral and social issues, and ultimately to attain lower levels of completed education." ECF No. 28-2 at 7. "They are also expected to have lower earnings as adults, poorer health, and an increased likelihood of criminal involvement." Id. But "[u]sing abortion to promote eugenic goals is morally and prudentially debatable." Planned Parenthood of Ind. & Ky., Inc. v. Comm'r of Ind. State Dep't of Health, 917 F.3d 532, 536 (7th Cir. 2018) (Easterbrook, J., dissenting); see also Box v. Planned Parenthood of Ind. & Ky., Inc., 139 S. Ct. 1780, 1790 (2019) (Thomas, J., concurring) ("[A]bortion has proved to be a disturbingly effective tool for implementing the discriminatory preferences that undergird eugenics."). Though eugenics were once fashionable in the Commanding Heights and High Court, they hold less purchase after the conflict, carnage, and casualties of the *last* century revealed the bloody consequences of Social Darwinism practiced by would-be Übermenschen. Cf. Buck v. Bell, 274 U.S. 200, 207 (1927) ("It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes.").

Defendants are correct that one purpose of injunctive relief is to preserve the status quo. *See, e.g., City of Dallas v. Delta Air Lines, Inc.*, 847 F.3d 279, 285 (5th Cir. 2017). But the "status quo" to be restored is "the last peaceable uncontested status existing between the parties before the

dispute developed." *Texas v. Biden*, No. 2:21-CV-067-Z, 2022 WL 17718634, at *9 (N.D. Tex. Dec. 15, 2022) (internal marks omitted); *see also Texas v. United States*, 40 F.4th 205, 220 (5th Cir. 2022) (the relevant status quo is the one "absent the unlawful agency action"); *Wages & White Lion*, 16 F.4th at 1144 ("In other words, 'the relief sought here would simply suspend *administrative* alteration of the *status quo*."") (quoting *Nken*, 556 U.S. at 430 n.1); *Callaway*, 489 F.2d at 576 ("If the currently existing status quo itself is causing one of the parties irreparable injury, it is necessary to alter the situation so as to prevent the injury."). "[P]arties could otherwise have no real opportunity to seek judicial review except at their peril." Mila Sohoni, *The Power to Vacate a Rule*, 88 GEO. WASH. L. REV. 1121, 1157–58 (2020). Chemical abortion is only the status quo insofar as Defendants' unlawful actions and their delay in responding to Plaintiffs' petitions have made it so. The fact that injunctive relief could upset this "status quo" is therefore an insufficient basis to deny injunctive relief.

G. A Stay Under Section 705 of the APA Is More Appropriate Than Ordering Withdrawal or Suspension of FDA's Approval

The Motion asks for injunctive relief but goes as far as requesting the Court to order Defendants to "withdraw or suspend the approvals of chemical abortion drugs, and remove them from the list of approved drugs." ECF No. 7 at 7. Singular equitable relief is "commonplace" in APA cases and is often "necessary to provide the plaintiffs" with "complete redress." *E. Bay Sanctuary Covenant v. Biden*, 993 F.3d 640, 681 (9th Cir. 2021) (internal marks omitted). Although the Court finds Plaintiffs have a substantial likelihood of prevailing on the merits, the Court instead exercises its authority under the APA to order less drastic relief. Section 705 of the APA provides:

When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings.

5 U.S.C. § 705 (emphasis added).

The Fifth Circuit has acknowledged "meaningful differences between an injunction, which is a 'drastic and extraordinary remedy,' and vacatur, which is 'a less drastic remedy.'" Texas v. Biden, 2022 WL 17718634 at *7 (quoting Texas v. United States, 40 F.4th at 219). Whereas an injunction "tells someone what to do or not to do," a vacatur only reinstates "the status quo absent the unlawful agency action and neither compels nor restrains further agency decision-making." *Id.* (internal marks omitted). A Section 705 stay can "be seen as an interim or lesser form of vacatur under Section 706." Id. "Just as a preliminary injunction is often a precursor to a permanent injunction, a stay under Section 705 can be viewed as a precursor to vacatur under Section 706." Id.; see also Nken, 556 U.S. at 428–29 (a stay "temporarily suspend[s] the source of authority to act — the order or judgment in question — not by directing an actor's conduct"). "Motions to stay agency action pursuant to [Section 705] are reviewed under the same standards used to evaluate requests for interim injunctive relief." Id. at *10 (citing Affinity Healthcare Servs., Inc. v. Sebelius, 720 F. Supp. 2d 12, 15 n.4 (D.D.C. 2010)); see also Nken, 556 U.S. at 434; Texas v. U.S. Env't *Prot. Agency*, 829 F.3d at 435. Because the Court finds injunctive relief is generally appropriate, Section 705 plainly authorizes the lesser remedy of issuing "all necessary and appropriate process" to postpone the effective date of the challenged actions. "Courts — including the Supreme Court — routinely stay *already-effective* agency action under Section 705." *Id.* at *8 (emphasis added) (collecting cases).

Accordingly, the Court hereby **STAYS** the effective date of FDA's September 28, 2000, Approval of mifepristone and all subsequent challenged actions related to that approval — *i.e.*, the 2016 Changes, the 2019 Generic Approval, and the 2021 Actions. This Court acknowledges that its decision in *Texas v. Biden* has been appealed to the Fifth Circuit. *See* 2:21-CV-067-Z, ECF No. 184 (Feb. 13, 2023). If the Fifth Circuit reverses this Court's Section 705 analysis, the Court clarifies that it alternatively would have ordered Defendants to suspend the chemical abortion approval and all subsequent challenged actions related to that approval until the Court can render

CONCLUSION

a decision on the merits.

For the foregoing reasons, the Court **GRANTS** the Motion **IN PART**. FDA's approval of mifepristone is hereby **STAYED**. The Court **STAYS** the applicability of this opinion and order for seven (7) days to allow the federal government time to seek emergency relief from the United States Court of Appeals for the Fifth Circuit.

SO ORDERED.

April 7, 2023

MATTHEW J. KACSMARYK UNITED STATES DISTRICT JUDGE

MANTROMANT

United States Court of Appeals

| for | the | F | ifth | Circi | ıí |
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United States Court of Appeals Fifth Circuit

FILED

April 12, 2023

No. 23-10362

Lyle W. Cayce Clerk

ALLIANCE FOR HIPPOCRATIC MEDICINE; AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS; AMERICAN COLLEGE OF PEDIATRICIANS; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS; SHAUN JESTER, D.O.; REGINA FROST-CLARK, M.D.; TYLER JOHNSON, D.O.; GEORGE DELGADO, M.D.,

Plaintiffs—Appellees,

versus

FOOD & DRUG ADMINISTRATION; ROBERT M. CALIFF, Commissioner of Food and Drugs; Janet Woodcock, M.D., in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration; Patrizia Cavazzoni, M.D., in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; United States Department of Health and Human Services; Xavier Becerra, Secretary, U.S. Department of Health and Human Services,

Defendants—Appellants,

versus

DANCO LABORATORIES, L.L.C.,

Intervenor—Appellant.

Appeal from the United States District Court for the Northern District of Texas USDC No. 2:22-CV-223

UNPUBLISHED ORDER

Before Haynes,* Engelhardt, and Oldham, Circuit Judges.

Per Curiam:

For the reasons given below, IT IS ORDERED that defendants' motions for a stay pending appeal are GRANTED IN PART. At this preliminary stage, and based on our necessarily abbreviated review, it appears that the statute of limitations bars plaintiffs' challenges to the Food and Drug Administration's approval of mifepristone in 2000. In the district court, however, plaintiffs brought a series of alternative arguments regarding FDA's actions in 2016 and subsequent years. And the district court emphasized that its order separately applied to prohibit FDA's actions in and after 2016 in accordance with plaintiffs' alternative arguments. As to those alternative arguments, plaintiffs' claims are timely. Defendants have not shown that plaintiffs are unlikely to succeed on the merits of their timely challenges. For that reason, and as more fully explained below, defendants' motions for a stay pending appeal are DENIED IN PART. Defendants' alternative motions for an administrative stay are DENIED AS MOOT. Plaintiffs' motion to dismiss the appeal is DENIED. The appeal is EXPEDITED to the next available Oral Argument Calendar.

^{*} JUDGE HAYNES concurs only in part: she concurs in the grant of the expedited appeal and the denial of the motion to dismiss. With respect to the request for a stay of the district court's order, as a member of the motions panel, she would grant an administrative stay for a brief period of time and defer the question of the stay pending appeal to the oral argument merits panel which receives this case.

I.

A.

Congress delegated to the Food and Drug Administration ("FDA") the responsibility to ensure that "new drugs" are "safe and effective." 21 U.S.C. §§ 321(p), 355; see also id. § 393(b)(2)(B). When making its approval determination, FDA evaluates whether a new drug application ("NDA") includes scientific evidence demonstrating that the drug is safe and effective for its intended uses. Id. § 355(d); see also 21 C.F.R. §§ 314.50, 314.105(c). Similarly, when a sponsor submits a supplemental new drug application ("SNDA") proposing changes to the conditions of approval for a drug (such as changes to a drug's labeling or FDA-imposed restrictions), FDA reviews the scientific evidence to support the changes. See 21 C.F.R. § 314.70. To approve a generic version of a previously approved drug, FDA reviews whether an abbreviated new drug application ("ANDA") contains information showing that the proposed generic drug is materially the "same" as the approved drug. 21 U.S.C. § 355(j)(2).

In 1992, FDA promulgated the so-called "Subpart H" regulations. Subpart H accelerates approval of drugs "that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy)." 21 C.F.R. § 314.500. Originally, Subpart H was intended to promote rapid approval for life-saving HIV-AIDS drugs. But given that Subpart H approvals were accelerated, FDA recognized that it would need post-approval safety measures. These post-approval safety measures would "assure safe use" of the quickly approved Subpart H drugs. Id. § 314.520. In 2007, Congress ratified these post-approval safety measures as "risk evaluation and

mitigation strategies" ("REMS"), which "ensure that the benefits of the drug outweigh the risks." 21 U.S.C. § 355-1(a)(1)-(2).

В.

In 2000, FDA approved mifepristone to be marketed with the brand name Mifeprex under Subpart H (the "2000 Approval"). See 21 C.F.R. § 314.500; FDA Add. 181.1 In the 2000 Approval, FDA concluded that pregnancy is a "life-threatening illness," triggering an accelerated approval of mifepristone under Subpart H. FDA Add. 186. FDA also concluded that a variety of post-approval restrictions on Mifeprex were required "to assure safe use." 21 C.F.R. § 314.520. As noted in the previous section, today we call such post-approval restrictions "REMS." The 2000 Approval imposed several REMS, including: (1) limiting the drug to pregnant women and girls for use through 49 days gestation; (2) requiring three in-person office visits, the first to administer mifepristone, the second to administer misoprostol, and the third to assess any complications and ensure there were no fetal remains in the womb; (3) requiring the supervision of a qualified physician; and (4) requiring the reporting of all adverse events from the drugs. FDA Add. 181-91. FDA granted Danco Laboratories, LLC, an exclusive license to manufacture, market, and distribute Mifeprex in the United States. FDA Add. 109.

In 2002, two of the plaintiff associations in this case filed a citizen petition challenging the 2000 Approval (the "2002 Citizen Petition"). See 21 C.F.R. § 10.25(a); PI App. 280–375. Roughly fourteen years later, FDA denied the 2002 Citizen Petition (the "2016 Petition Denial"). FDA Add.

¹ Citations to the addendum to FDA's emergency motion for a stay pending appeal are denoted "FDA Add." Citations to the appendix to plaintiffs' motion for a preliminary injunction are denoted "PI App."

804–36. And on the very same day in March 2016, FDA approved several major changes to mifepristone's approved conditions of use, including its REMS. Specifically, FDA removed four of the original safety restrictions by (1) increasing the maximum gestational age at which a woman can use the drug from 49 to 70 days; (2) reducing the number of required in-person office visits from three to one; (3) allowing non-doctors to prescribe and administer the chemical abortions drugs; and (4) eliminating the requirement for prescribers to report non-fatal adverse events from chemical abortion (the "2016 Major REMS Changes"). FDA Add. 777–802.

In March 2019, one of the plaintiff associations filed a second citizen petition challenging the 2016 Major REMS Changes (the "2019 Citizen Petition"). FDA Add. 192–217. That petition asked FDA to "restore" the 2000 Approval's REMS and "retain" a requirement that mifepristone be dispensed to patients in person. FDA Add. 192.

In April 2019, FDA approved GenBioPro, Inc's ANDA for a generic version of mifepristone (the "2019 Generic Approval"). PI App. 694–708. GenBioPro's generic version of mifepristone has the same labeling and REMS requirements as Danco's Mifeprex.

In April 2021, FDA announced that it would "exercise enforcement discretion" to allow "dispensing mifepristone through the mail... or through a mail-order pharmacy" during the COVID-19 pandemic (the "2021 Mail-Order Decision"). PI App. 713–15. FDA took this action in response to a letter from the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine. PI App. 710–11.

Later that year, in December 2021, FDA denied almost all of the 2019 Citizen Petition (the "2021 Petition Denial"). FDA Add. 837-76. In particular, FDA expressly rejected the 2019 Citizen Petition's request to keep the in-person dispensing requirements and announced that the agency

had concluded that "the in-person dispensing requirement is no longer necessary." FDA Add. 842.

Finally, in January 2023, FDA approved a modified REMS for mifepristone lifting the in-person dispensing requirement. *See REMS Single Shared System for Mifepristone 200 mg* (Jan. 2023), https://perma.cc/MJT5-35LF (the "2023 Mail-Order Decision").²

C.

In November 2022, plaintiffs (physicians and physician organizations) filed this suit against FDA, HHS, and a several agency heads in the official capacities. Plaintiffs first challenged FDA's 2000 Approval of the drug. But they also requested multiple grounds of alternative relief for FDA's subsequent actions. Immediately after filing, plaintiffs moved for a preliminary injunction ordering FDA to withdraw or suspend (1) FDA's 2000 Approval and 2019 Generic Approval, (2) FDA's 2016 Major REMS Changes, and (3) FDA's 2021 Mail-Order Decision and its 2021 Petition Denial of the 2019 Citizen Petition. If that's confusing, we hope this chart helps:

² Danco suggests the 2023 Mail-Order Decision moots part of plaintiffs' claims. See Danco Stay App. 22. We disagree. The Supreme Court has explicitly instructed this court to review a new agency action finalized after litigation commenced and while the appeal was pending because this decision was a "final agency action" for purposes of 5 U.S.C. § 704. Biden v. Texas, 142 S. Ct. 2528, 2544-45 (2022) (quotation omitted).

| Event | Citation | Description | |
|-----------------------------|--------------------------------|---|--|
| 2000 Approval | FDA Add. 181–91 | Approved mifepristone with these REMS: (1) pregnancies under 50 days gestation; (2) three in-person office visits; (3) supervision of a qualified physician; and (4) reporting of all adverse events | |
| 2002 Citizen Petition | PI App. 280–375 | Plaintiffs' challenge to 2000 Approval | |
| 2016 Petition Denial | FDA Add. 804-36 | FDA denial of 2002 Citizen Petition | |
| 2016 Major REMS Changes | FDA Add. 768, 777-802 | FDA changed four of the 2000 Approval's REMS: (1) increased maximum gestational age to 70 days; (2) reduced required in-person office visits to one; (3) allowed non-doctors to prescribe and administer mifepristone; and (4) eliminated reporting of non-fatal adverse events | |
| 2019 Citizen Petition | FDA Add. 192-217 | Plaintiffs' challenge to 2016 Major REMS Changes | |
| 2019 Generic Approval | PI App. 694–708 | FDA ANDA Approval Letter for mifepristone generic to GenBioPro, Inc. | |
| 2021 Mail-Order Decision | PI App. 713–15 | FDA announces "enforcement discretion" to allow mifepristone to be dispensed through the mail during COVID-19 | |
| 2021 Petition Denial | FDA Add. 837-76 | FDA denial of almost all of the 2019 Citizen Petition, including plaintiffs' request to keep the in-person dispensing requirements | |
| 2023 Mail-Order Decision | https://perma.cc/MJT5- 35LF | FDA permanently removed the in-person dispensing REMS | |

On April 7, 2023, the district court entered an order staying the effective date of the 2000 Approval and each of the subsequent challenged actions.³ The district court stayed its own order for seven days to allow the defendants time to appeal.

II.

FDA and Danco ("stay applicants" or "applicants") ask us to stay the district court's order pending appeal. Our power to grant a stay is inherent. See In re McKenzie, 180 U.S. 536, 551 (1901); Scripps-Howard Radio v. FCC, 316 U.S. 4, 10–14 (1942). It's also statutory. See FED. R. APP. P. 8; 28 U.S.C. § 1651; 5TH CIR. R. 27.3; see also 16A CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE & PROCEDURE § 3954 (5th ed. Apr. 2022 update).

But we grant stays "only in extraordinary circumstances." Williams v. Zbaraz, 442 U.S. 1309, 1311 (1979) (Stevens, J., in chambers); see also Graves v. Barnes, 405 U.S. 1201, 1203 (1972) (Powell, J., in chambers) (same); Ruckelshaus v. Monsanto Co., 463 U.S. 1315, 1316 (1983) (Blackmun, J., in chambers) (same). This rule reflects the fact that "a stay is not a matter of right, even if irreparable injury might otherwise result." Virginian Ry. Co. v. United States, 272 U.S. 658, 672 (1926). Instead, a stay requires "an exercise of judicial discretion." Ibid. A "decree creates a strong presumption of its own correctness," which often counsels against a stay. Id. at 673.

³ As both parties recognize, this order would have the practical effect of an injunction because it would remove mifepristone from the market. Plaintiffs filed a motion to dismiss applicants' appeal on the theory that § 705 stays are not sufficient to trigger our interlocutory appellate jurisdiction under 28 U.S.C. § 1292(a). We disagree. *See Abbott v. Perez*, 138 S. Ct. 2305, 2319–20 (2018) (explaining that the "practical effect" test of 28 U.S.C. §§ 1292(a)(1) and 1293 "prevents [the] manipulation" that could occur "if the availability of interlocutory review depended on the district court's use of the term 'injunction'").

The Supreme Court has prescribed "four traditional stay factors" that govern this equitable discretion in most civil cases. *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2487 (2021) (quotation omitted); *see also Hilton v. Braunskill*, 481 U.S. 770, 776–77 (1987); *Rose v. Raffensperger*, 143 S. Ct. 58, 59 (2022) (reversing stay of an injunction after the court of appeals failed to analyze the traditional stay factors). Those factors are:

(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

Nken v. Holder, 556 U.S. 418, 426 (2009) (quoting Hilton, 481 U.S. at 776); see also Whole Woman's Health v. Jackson, 141 S. Ct. 2494, 2495 (2021). Although no factor is dispositive, the likelihood of success and irreparable injury factors are "the most critical." Nken, 556 U.S. at 434. Success on either factor requires that the stay seeker make a strong not merely "possib[le]" showing. Ibid.

In these respects, stays might appear identical to preliminary injunctions. Similar factors govern both and both require an "extraordinary" deployment of judicial discretion. Winter v. Nat. Res. Def. Council, 555 U.S. 7, 24 (2008). But the two are not "one and the same." Nken, 556 U.S. at 434. A stay "operates upon the judicial proceeding itself," not on the conduct of a particular actor. Id. at 428. And, once one party has won an injunction, proof burdens reverse. It is the enjoined party who seeks a stay, or FDA and Danco here, who must carry the burden of proving that the Nken factors command us to issue one. See Landis v. N. Am. Co., 299 U.S. 248, 255 (1936).

If the stay applicants show that circumstances require a stay of some but not all of the district court's order, we may, in our discretion, "tailor a stay so that it operates with respect to only some portion of the proceeding." Trump v. Int'l Refugee Assistance Project, 137 S. Ct. 2080, 2087 (2017) (per curiam) (quoting Nken, 556 U.S. at 428).

We find that FDA and Danco succeed only in part.

III.

Regarding likelihood to succeed on the merits, the stay applicants raise four arguments. They contend (A) plaintiffs are unlikely to defend the district court's stay because they lack standing. They next contend (B) plaintiffs' claims are untimely. Then they claim (C) plaintiffs' claims are unexhausted. Finally, applicants contend (D) FDA's actions are not arbitrary, capricious, or otherwise contrary to law. We consider each in turn.

Α.

We begin with Article III standing. To bring their claims in federal court, plaintiffs must satisfy the familiar tripartite test: they must show they suffered an injury in fact, that's fairly traceable to the defendants, and that's likely redressable by a favorable decision. See Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871 (1990). Importantly, only one plaintiff needs to have standing to present a valid case or controversy. See Rumsfeld v. Forum for Acad. & Institutional Rts., Inc., 547 U.S. 47, 52 n.2 (2006).

Plaintiffs and the district court offered numerous theories of standing. At this preliminary, emergency stage, we are unpersuaded by applicants' contentions that all of these theories fail to create a justiciable case or controversy. We need only consider two: (1) injuries to doctors and (2) injuries to the plaintiff medical associations.⁴

⁴ We are cognizant of the fact that the Supreme Court has disavowed the theories of third-party standing that previously allowed doctors to raise patients' claims in abortion

1.

First, it appears that the individual plaintiffs and doctors in plaintiff associations have standing to challenge FDA's actions.

To allege an injury in fact, these doctors must show they have suffered an "invasion of a legally protected interest" that is both "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339 (2016) (quotation omitted). Plaintiffs must identify specific injuries that go beyond "general averments" or "conclusory allegations." *Friends of the Earth, Inc. v. Laidlaw Env't Servs.* (TOC), Inc., 528 U.S. 167, 184 (2000) (quoting Lujan, 497 U.S. at 888). Where a plaintiff seeks prospective relief and hence points to future injuries, the Supreme Court has emphasized that "threatened injury must be certainly impending to constitute injury in fact, and that allegations of possible future injury are not sufficient." Clapper v. Amnesty Int'l USA, 568 U.S. 398, 409 (2013) (quotation omitted).

Here, FDA approved the "Patient Agreement Form," part of the REMS for mifepristone, which provides:

cases. See Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2275 & n.61 (2022). So we express no opinion on plaintiffs' third-party standing theories.

PATIENT AGREEMENT FORM

Mifepristone Tablets, 200 mg

Healthcare Providers: Counsel the patient on the risks of mifepristone. Both you and the patient must provide a written or electronic signature on this form.

Patient Agreement:

- I have decided to take mifepristone and misoprostol to end my pregnancy and will follow my healthcare provider's advice about when to take each drug and what to do in an emergency.
- I understand:
 - I will take mifepristone on Day 1.
 - b. I will take the misoprostol tablets 24 to 48 hours after I take mifepristone.
- 3. My healthcare provider has talked with me about the risks, including:
 - heavy bleeding
 - infection
- 4. I will contact the clinic/office/provider right away if in the days after treatment I have:
 - · a fever of 100.4°F or higher that lasts for more than four hours
 - heavy bleeding (soaking through two thick full-size sanitary pads per hour for two hours in a row)
 - severe stomach area (abdominal) pain or discomfort, or I am "feeling sick," including weakness, nausea, vomiting, or diarrhea, more than 24 hours after taking misoprostol
 - these symptoms may be a sign of a serious infection or another problem (including an
 ectopic pregnancy, a pregnancy outside the womb).

My healthcare provider has told me that these symptoms listed above could require emergency care. If I cannot reach the clinic/office/provider right away, my healthcare provider has told me who to call and what to do.

- I should follow up with my healthcare provider about 7 to 14 days after I take mifepristone to be sure that my pregnancy has ended and that I am well.
- 6. I know that, in some cases, the treatment will not work. This happens in about 2 to 7 out of 100 women who use this treatment. If my pregnancy continues after treatment with mifepristone and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy.
- If I need a surgical procedure because the medicines did not end my pregnancy or to stop heavy bleeding, my healthcare provider has told me whether they will do the procedure or refer me to another healthcare provider who will.
- 8. I have the MEDICATION GUIDE for mifepristone.
- 9. My healthcare provider has answered all my questions.

| Datiant Cianatura | Detient Name (asint): | Data |
|--------------------|-----------------------|-------|
| Patient Signature: | Patient Name (print): | Date: |

2023 Mail-Order Decision at 10. FDA thus cannot deny that serious complications from mifepristone are certainly impending. Those complications are right there on the "Patient Agreement Form" that FDA itself approved and that Danco requires every mifepristone user to sign. According to the applicants, more than 5,000,000 women have taken this drug since the 2000 Approval. FDA Stay App. 1. That means that, again according to the applicants' own information, between 100,000 (2%) and

350,000 (7%) of mifepristone users had unsuccessful chemical abortions and had to "talk with [their] provider[s] about a surgical procedure to end [their] pregnanc[ies]." 2023 Mail-Order Decision at 10. And where did those hundreds of thousands of women go for their "surgical procedures"? Again, we need not speculate because the 2016 Major REMS Changes, the 2021 Petition Denial, and the 2023 Mail-Order Decision all allow non-doctors to prescribe mifepristone. The women who use this drug cannot possibly go back to their non-doctor-prescribers for surgical abortions, so again, as the "Patient Agreement Form" itself says, they must instead seek "emergency care" from a qualified physician.

The plaintiff emergency room doctors have a concrete, particularized injury since they have provided—and with certainty will continue to provide—the "emergency care" that applicants specified in the "Patient Agreement Form." PI App. 167, 169, 194, 206. Mifepristone users who present themselves to the plaintiffs have required blood transfusions, overnight hospitalization, intensive care, and even surgical abortions. PI App. 205–06. As one doctor testified:

For example, in one month while covering the emergency room, my group practice admitted three women to the hospital. Of the three women admitted in one month due to chemical abortion complications, one required admission to the intensive care unit for sepsis and intravenous antibiotics, one required a blood transfusion for hemorrhage, and one required surgical completion for the retained products of conception (*i.e.*, the doctors had to surgically finish the abortion with a suction aspiration procedure).

PI App. 206.

Another doctor testified:

[O]ne of my patients had obtained mifepristone and misoprostol from a website, without an in-person

visit.... After taking the chemical abortion drugs, she began having very heavy bleeding followed by significant abdominal pain and a fever. When I saw her in the emergency room, she had evidence of retained pregnancy tissue along with endometritis, an infection of the uterine lining. She also had acute kidney injury, with elevate creatinine. She required a dilation and curettage (D&C) surgery to finish evacuating her uterus of the remaining pregnancy tissue and hospitalization for intravenous (IV) antibiotics, IV hydration, and a blood transfusion. I spent several hours with her the day of her surgery/hospital admission, keeping me from my primary patient responsibilities in the labor and delivery unit and requiring me to call in an additional physician to help cover those responsibilities.

PI App. 194–95. As a result of FDA's failure to regulate this potent drug, these doctors have had to devote significant time and resources to caring for women experiencing mifepristone's harmful effects. This harm is sufficiently concrete.

A second independent injury from the adverse effects of mifepristone is the "enormous stress and pressure" physicians face in treating these women. PI App. 215. One doctor said the strain "is some of the most emotionally taxing work I have done in my career." PI App. 880. Thus, this is an independent injury because FDA's actions "significantly affect[]" the doctors' "quality of life." *Sierra Club v. Morton*, 405 U.S. 727, 734–35 (1972).

The doctors offered specific facts to explain this stress. Women who take these drugs are susceptible to "torrential bleeding." PI App. 170, 215. In fact, "the risk of severe bleeding with chemical abortion is five times higher than from surgical abortion." PI App. 879. And these situations can quickly go from bad to worse. As one doctor testified:

One of my patients, who was about nine weeks pregnant, had previously been treated by hospital staff for a pulmonary

embolism with anti-coagulants. She was advised that she could not seek a chemical abortion because it was contraindicated due to the medications; yet the woman left the hospital and sought an abortion at Planned Parenthood of Indiana. The woman was given mifepristone by the doctor at Planned Parenthood and took the drug. The woman called an Uber for a ride home from Planned Parenthood. The woman began to experience bleeding and other adverse effects from the mifepristone. The woman's Uber driver did not take her home because she was so ill and instead brought her to the hospital's emergency department. At the hospital, the woman came under my care. The woman had not yet taken the second abortion drug, misoprostol. I treated the patient for the adverse effects she suffered and told her not to take the misoprostol given to her by Planned Parenthood because of the grave risk that she could bleed out and die.

PI App. 216–17. Another doctor recounted an experience where he treated a patient—who "suffered from two weeks of moderate to heavy bleeding, and then developed a uterine infection"—by providing her "with intravenous antibiotics" and performing a D&C procedure. PI App. 886. If the patient waited a few more days to go to the hospital, the doctor predicted that "she could have been septic and died." PI App. 886. Another doctor testified that he has encountered "at least a dozen cases of life-threatening complications" from these drugs, and the frequency of these emergency situations has only increased over time. PI App. 865.

The risks are only exacerbated for women who have ectopic pregnancies. PI App. 207. This occurs in approximately two percent of pregnancies. PI App. 539. As one doctor explained:

Chemical abortion drugs will not effectually end an ectopic pregnancy because they exert their effects on the uterus, which leaves women at risk of severe harm from hemorrhage due to tubal rupture, in need of emergent surgery or potentially at risk of death. Failure to perform an ultrasound prior to prescribing abortion drugs will cause some women to remain undiagnosed and at high risk for these adverse outcomes.

PI App. 208. The risks are greater under FDA's relaxed standards. That is because "without an in-person examination, it is impossible to rule out an ectopic pregnancy," placing a woman "at an increased risk of rupture or even death." PI App. 886.

The doctors also face an injury from the irreconcilable choice between performing their jobs and abiding by their consciences. These doctors structured their careers so they would not have to administer abortions. And yet, because women often come to hospitals when they experience complications from these drugs, these doctors sometimes have no other choice but to perform surgical abortions. As one doctor testified:

The FDA's expansion of chemical abortions also harms my conscience rights because it could force me to have to surgically finish an incomplete elective chemical abortion. I object to abortion because it ends a human life. My moral and ethical obligation to my patients is to promote human life and health. But the FDA's actions may force me to end the life of a human being in the womb for no medical reason.

PI App. 209–10. And this harm is not speculative. Several doctors confirmed that they have had to surgically complete an abortion or remove an unborn child. PI App. 886, 205. As one doctor testified: "In my practice, I have cared for at least a dozen women who have required surgery to remove retained pregnancy tissue after a chemical abortion. Sometimes this includes the embryo or fetus, and sometimes it is placental tissue that has not been completely expelled." PI App. 205. That same doctor described how she had to "perform[] a suction aspiration procedure" on one patient who took the pill but needed surgery to complete the abortion. PI App. 206. Others have seen it firsthand. One doctor recounted a time where a woman came to the

emergency room "with heavy vaginal bleeding and unstable vital signs as a result of taking chemical abortion drugs." PI App. 195. When the woman arrived in the emergency room, the baby in her womb was not dead; the doctors were "able to detect a fetal heartbeat." PI App. 195. But due to the mother's unstable condition, the doctors "had no choice but to perform an emergency D&C." PI App. 196. The doctor testified that her colleague "felt as though she was forced to participate in something that she did not want to be a part of—completing the abortion." PI App. 196.

And not only have these doctors suffered injuries in the past, but it's also inevitable that at least one doctor in one of these associations will face a harm in the future. Cf. City of Los Angeles v. Lyons, 461 U.S. 95 (1983). Here, the plaintiff-doctors have "'set forth' by affidavit or other evidence 'specific facts'" that they are certain to see more patients. Clapper, 568 U.S. at 411 (quoting Lujan v. Defs. of Wildlife, 504 U.S. 555, 561 (1992)). That's because FDA has removed almost all of mifepristone's REMS and thus enabled women to (1) get the drug without ever talking to a physician, (2) take the drug without ever having a physical exam to ensure gestational age and/or an ectopic pregnancy, and (3) attempt to complete the chemical abortion regimen at home; FDA has also (4) directed the hundreds of thousands of women who have complications to seek "emergency care" from the plaintiffs and plaintiffs' hospitals. Several doctors testified that they have seen an increasing number of women coming to the emergency room with complications from chemical abortions due to FDA's virtual elimination of controls on the dispensing and administration of the drugs. PI App. 194, 205, 215, 866. And given how many women these doctors have seen in emergency departments in the past, these doctors quite reasonably know with statistical certainty-again, a statistic estimated on Mifeprex's own "Patient Agreement Form"—that women will continue needing plaintiffs' "emergency care." See PI App. 205, 215, 868. The crisis is "concededly

ongoing." Friends of the Earth, 528 U.S. at 184. Accordingly, plaintiffs face a "substantial risk" of recurrence. Susan B. Anthony List v. Driehaus, 573 U.S. 149, 158 (2014) (quotation omitted).

And even if one of the named doctors never sees another patient, it's inevitable that one of the thousands of doctors in plaintiff associations will. For example, one of the plaintiff associations, the American Association of Pro-Life Obstetricians & Gynecologists, "is the largest organization of prolife obstetricians and gynecologists" and has "more than 7,000 medical professionals nationwide." PI App. 165. The Christian Medical and Dental Association has "more than 600 physicians and approximately 35 OBGYNs." PI App. 179. The American College of Pediatricians has a membership of "more than 600 physicians and other healthcare professionals." PI App. 187. These associations presented affidavits from individual members, elucidating the various harms discussed herein. See Friends of the Earth, 528 U.S. at 183-84. Thus, they have associational standing to sue on behalf of their members. See N.Y. State Club Ass'n, Inc. v. City of New York, 487 U.S. 1, 9 (1988); Hunt v. Wash. State Apple Advertising Comm'n, 432 U.S. 333, 343 (1977). That means that so long as one doctor among the thousands of members in these associations faces an injury, Article III is satisfied. See Rumsfeld, 547 U.S. at 52 n.2.

The doctors can also show that these injuries are traceable to FDA regulations and redressable by this court. See Defs. of Wildlife, 504 U.S. at 560–61. That's because the 2016 Major REMS Changes, the 2021 Petition Denial, and the 2023 Mail-Order Decision all empower non-doctors to prescribe mifepristone and thus shift the costs of the drug onto the plaintiff physicians who must manage the aftermath. See, e.g., PI App. 218 ("I spent a significant amount of time that day working to save her life from unnecessary complications due to the irresponsible administration and use of mifepristone and misoprostol. As a result of the significant time that I devoted to that

patient, my time and attention was taken away from other patients, who also need my care."); PI App. 867 ("Because more women [who take mifepristone] are unnecessarily presenting in the emergency department, more of my time and attention is taken away from other patients who need it."). In this way, "[t]he FDA's actions have created a culture of chaos for emergency room physicians." PI App. 867. And we're capable of redressing plaintiffs' injuries by restoring the 2000 Approval's REMS. Accordingly, at this stage, applicants have not shown that all of the plaintiffs lack standing.

We hasten to emphasize the narrowness of this holding. We do not hold that doctors necessarily have standing to raise their patients' claims. See supra n.4. We do not hold that doctors have constitutional standing whenever they're called upon to do their jobs. And we do not hold that doctors have standing to challenge FDA's actions whenever the doctor sees a patient experiencing complications from an FDA-approved drug. Rather, we hold that on the record before us applicants know that hundreds of thousands of women will—with applicants' own statistical certainty—need emergency care on account of applicants' actions. And because applicants chose to cut out doctors from the prescription and administration of mifepristone, plaintiff doctors and their associations will necessarily be injured by the consequences. This is an exceedingly unusual regime. In fact, as far as the record before us reveals, FDA has not structured the distribution of any comparable drug in this way.

FDA's principal contention to the contrary is that mifepristone is comparable to "ibuprofen." FDA Stay App. 1. The theory appears to be that we cannot recognize plaintiffs' standing here without opening a pandora's box in which doctors have standing to litigate everything at all times, including the banalities of over-the-counter Advil.

We disagree because FDA's own documents show that mifepristone bears no resemblance to ibuprofen. In the 2000 Approval, FDA imposed a "Black Box" warning on mifepristone. FDA requires "Black Box" warnings when a drug "may lead to death or serious injury." 21 C.F.R. § 201.57(c)(1). In its 2000 Approval, FDA conditioned its approval of mifepristone on the inclusion of this "Black Box" warning:

"If Mifeprex results in incomplete abortion, surgical intervention may be necessary. Prescribers should determine in advance whether they will provide such care themselves or through other providers. Prescribers should also give patients clear instructions of whom to call and what to do in the event of an emergency following administration of Mifeprex.

Prescribers should make sure the patients receive and have an opportunity to discuss the Medication Guide and Patient Agreement."

FDA Add. 182. The 2016 Major REMS Changes relaxed many of the requirements for marketing and using mifepristone. But it retained this "Black Box" warning:

WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING

Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use. No causal relationship between the use of MIFEPREX and misoprostol and these events has been established.

- Atypical Presentation of Infection. Patients with serious bacterial infections (e.g., Clostridium sordellii) and sepsis can present without fever, bacteremia, or significant findings on pelvic examination following an abortion. Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise. A high index of suspicion is needed to rule out serious infection and sepsis [see Warnings and Precautions (5.1)].
- Bleeding. Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed. Advise patients to seek immediate medical attention if they experience prolonged heavy vaginal bleeding [see Warnings and Precautions (5.2)].

Because of the risks of serious complications described above, MIFEPREX is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the MIFEPREX REMS Program [see Warnings and Precautions (5.3)].

Before prescribing MIFEPREX, inform the patient about the risk of these serious events. Ensure that the patient knows whom to call and what to do, including going to an Emergency Room if none of the provided contacts are reachable, if she experiences sustained fever, severe abdominal pain, prolonged heavy bleeding, or syncope, or if she experiences abdominal pain or discomfort, or general malaise (including weakness, nausea, vomiting or diarrhea) for more than 24 hours after taking misoprostol.

Advise the patient to take the Medication Guide with her if she visits an emergency room or a healthcare provider who did not prescribe MIFEPREX, so that the provider knows that she is undergoing a medical abortion.

https://perma.cc/R56J-BHW4.

Ibuprofen's label, which FDA helpfully provided in its stay addendum, obviously bears no resemblance to the "Black Box" warning on mifepristone's label. FDA Add. 465–68. To the contrary, FDA has a special regulation regarding ibuprofen so all manufacturers of that over-the-counter medicine include the same information on their labels. *See* 21 C.F.R. § 201.326. It says nothing about REMS, surgery, emergencies, Emergency Rooms, or death.

In sum, applicants' own documents—from the "Patient Agreement Form" to the "Black Box" warning that have accompanied mifepristone

ever since the 2000 Approval up to and including today—prove that emergency room care is statistically certain in hundreds of thousands of cases. Plaintiff doctors have provided that emergency room care and are statistically certain to provide it in the future.

2.

Second, the associations have standing. As previously discussed, they have associational standing to sue on behalf of their members. See N. Y. State Club Ass'n, Inc., 487 U.S. at 9; Hunt, 432 U.S. at 343. The associations presented affidavits from individual member doctors who have suffered harms. See Friends of the Earth, 528 U.S. at 183–84. Accordingly, they have standing to sue on their members' behalf.

Plaintiff associations have also suffered independent injuries because FDA's actions have frustrated their organizational efforts to educate their members and the public on the effects of mifepristone. See Havens Realty Corp. v. Coleman, 455 U.S. 363, 379 (1982) (holding that housing non-profit had standing to challenge racial steering practices that impaired its ability "to provide counseling and referral services for low-and-moderate-income homeseekers"). As a result, plaintiff associations have expended "time, energy, and resources to compensate for this lack of information by conducting their own studies and analyses of available data" to "the detriment of other advocacy and educational efforts." PI App. 174. The Supreme Court has previously stated that such a "concrete and demonstrable injury to the organization's activities—with the consequent drain on the organization's resources—constitutes far more than simply a setback to the organization's abstract social interests," Havens, 455 U.S. at 379, even where the organizational interest is purely "noneconomic," id. at 379 n.20. Rather, under these circumstances, "there can be no question that the organization has suffered an injury in fact." *Id.* at 379.

This injury is also traceable to FDA's elimination of non-fatal adverse events in the 2016 Major REMS Changes. And it's redressable by an order vacating those changes. Accordingly, these associations also have standing.

B.

Next we turn to timeliness.

Everyone acknowledges that 28 U.S.C. § 2401(a)'s six-year limitations period applies to all of this case's challenged actions. And plaintiffs' right of action against the lion's share of the challenged actions are squarely within the six-year window. That includes all of plaintiffs' alternative arguments challenging the 2016 Major REMS Changes, the 2019 Generic Approval, the 2021 Mail-Order Decision, and the 2021 Petition Denial of the 2019 Citizen Petition.

True, FDA's March 2016 Major REMS Changes were promulgated more than six years before plaintiffs filed suit in November 2022. But Section 2401(a) instructs that the six-year period begins when "the right of action first accrues." "And '[t]he right of action first accrues on the date of the final agency action.'" *Texas v. Biden*, 20 F.4th 928, 951 n.3 (5th Cir. 2021), *rev'd on other grounds*, 142 S. Ct. 2528 (2022) (quoting *Wash. All. of Tech. Workers v. DHS*, 892 F.3d 332, 342 (D.C. Cir. 2018)). Though FDA promulgated the Major REMS Changes in 2016, the Agency didn't respond to plaintiffs' 2019 Petition challenging those changes until December 16, 2021. So plaintiffs' right of action against FDA's final decision first accrued in December of 2021. *See* 21 C.F.R. § 10.45. That's less than a year before plaintiffs sued, which is well within the limitations period.

Next, applicants claim that plaintiffs' primary challenges to the 2000 Approval and FDA's 2016 Petition Denial to their 2002 Citizen Petition are time-barred. Though admittedly a close question, we ultimately agree with applicants at this preliminary juncture.

Plaintiffs' right of action against the 2000 Approval and 2016 Petition Denial first accrued on March 29, 2016—the date FDA issued its final decision rejecting their 2002 Petition challenging the 2000 Approval. See 21 C.F.R. § 10.45. But plaintiffs didn't file suit until November 18, 2022, more than six months beyond the statute of limitations. The district court nevertheless found timely the plaintiffs' challenges to the 2000 Approval and the 2016 Petition Denial. How? First, the district court held that FDA "reopened" those decisions in 2016 and 2021, thus restarting the statute of limitations. Second—and alternatively—the district court decided plaintiffs were entitled to equitable tolling.

We consider each justification in turn.

First, reopening. "The reopen[ing] doctrine allows an otherwise untimely challenge to proceed where an agency has—either explicitly or implicitly—undertaken to reexamine its former choice." Nat'l Biodiesel Bd. v. EPA, 843 F.3d 1010, 1017 (D.C. Cir. 2016) (quotation omitted). Put simply, the purpose of the reopening doctrine is "to pinpoint an agency's final action in cases where the agency has addressed the same issue multiple times." Texas v. Biden, 20 F.4th at 951. The limitations period runs from the agency's earlier decision unless the later decision "opened the issue up anew." Ibid. (quotation omitted). This makes good sense: Because a key step in the timeliness inquiry is determining when an agency action became final, it's sometimes necessary to determine whether an agency's subsequent action "actually reconsidered" its former action, Growth Energy v. EPA, 5 F.4th 1, 21 (D.C. Cir. 2021) (per curiam) (quotation omitted), or merely "reaffirm[ed] its prior position," Sierra Club v. EPA, 551 F.3d 1019, 1024 (D.C. Cir. 2008) (quotation omitted); see also Texas v. Biden, 20 F.4th at 951 ("If the agency opened the issue up anew, and then reexamined and reaffirmed its prior decision, the agency's second action (the reaffirmance) is reviewable.... But if the agency merely reaffirmed its decision without really opening the decision back up and reconsidering it, the agency's initial action is the only final agency action to review." (quotation omitted)).

Courts have articulated various tests for determining whether an agency has reopened a prior decision. These tests fall into two general categories.

Under the first, courts look "to the entire context of the [relevant agency action including all relevant proposals and reactions of the agency to determine whether an issue was in fact reopened." Pub. Citizen v. Nuclear Regul. Comm'n, 901 F.2d 147, 150 (D.C. Cir. 1990); see also, e.g., id. at 150-53; Growth Energy, 5 F.4th at 21-22; Nat'l Ass'n of Reversionary Prop. Owners v. Surface Transp. Bd., 158 F.3d 135, 141-46 (D.C. Cir. 1998). An agency can reopen an earlier decision in many ways, but the quintessential example of this type of reopening is when an agency "hold[s] out [its prior rule] as a proposed regulation, offer[s] an explanation for its language, solicit[s] comments on its substance, and respond[s] to the comments in promulgating the regulation in its final form." Am. Iron & Steel Inst. v. EPA, 886 F.2d 390, 397 (D.C. Cir. 1989). Under the second reopening category, courts consider whether an agency "constructively reopened" its prior decision. Kennecott Utah Copper Corp. v. DOI, 88 F.3d 1191, 1214-15 (D.C. Cir. 1996). They do so by evaluating whether "the revision of accompanying regulations significantly alters the stakes of judicial review as the result of a change that could have not been reasonably anticipated." NRDC v. EPA, 571 F.3d 1245, 1266 (D.C. Cir. 2009) (quotation omitted).

Although a close call, we are unsure at this preliminary juncture and after truncated review that FDA reopened the 2000 Approval in its 2016 Major REMS Changes and its 2021 Petition Denial.

As for the first reopening test, neither the 2016 Major REMS Changes nor the 2021 Petition Denial appears to "substantive[ly] reconsider[]"

FDA's 2000 Approval. *Growth Energy*, 5 F.4th at 21. FDA's 2016 decision to relax many of the REMS was issued in response to Danco's supplemental application requesting as much. *See* PI App. 615–52. And FDA's 2021 Petition Denial was issued in response to plaintiffs' 2019 Citizen Petition asking FDA to "restore" the pre-2016 REMS—not revoke or reconsider FDA's underlying 2000 Approval. *See* PI App. 667–93. Therefore neither of the "relevant proposals" prompted FDA to reopen and reconsider its 2000 Approval. *Pub. Citizen*, 901 F.2d at 150.

That said, the district court correctly noted that FDA nevertheless "undertook a full review of the Mifepristone REMS Program" when it reviewed plaintiffs' 2019 Citizen Petition—even though the plaintiffs only asked FDA to restore the pre-2016 status quo ante. *See* PI App. 735–76; FDA Add. 22. In FDA's words:

In 2021, FDA also undertook a full review of the Mifepristone REMS Program. In conducting this review, FDA reviewed multiple different sources of information, including published literature, safety information submitted to the Agency during the COVID-19 PHE, FDA Adverse Event Reporting System (FAERS) reports, the first REMS assessment report for the Mifepristone REMS Program, and information provided by advocacy groups, individuals, and the Plaintiffs in ongoing litigation, as well as information submitted by the sponsors of the NDA and the ANDA[.]

PI App. 735. And after conducting this unrequested "full review" of the REMS Program, FDA (*inter alia*) added two modifications to the REMS Program that plaintiffs never even mentioned in their 2019 Citizen Petition, including "a requirement that pharmacies that dispense the drug be specially certified." PI App. 736; *see also id.* at 735 n.11 (acknowledging that "this was not raised in your Petition"). All of this suggests FDA went back to the beginning, including its very first REMS report, and conducted an

independent review that far exceeded the issues raised in the 2019 Citizen Petition.

Especially because the dangerousness of a drug is grounds to withdraw its approval, see 21 U.S.C. § 355(e)—and REMS are required to "ensure that the benefits of the drug outweigh the risks," id. § 355-1(a)(1)–(2)—plaintiffs reasonably argue that FDA's 2021 "full review" of the entire REMS Program was in effect a reconsideration of FDA's 2000 Approval. Indeed, plaintiffs might very well prevail on that claim later in this litigation. But at this early juncture—and in light of our necessarily truncated review—we are not yet confident enough to say that viewed in "the entire context," FDA "has undertaken a serious, substantive reconsideration of the [2000 Approval]" rather than "incremental adjustments to existing regulations." Texas v. Biden, 20 F.4th at 952–93 (quotation omitted).

The result is the same under the second reopening test. Recall that under the second test, "[a] constructive reopening occurs if the revision of accompanying regulations significantly alters the stakes of judicial review as the result of a change that could have not been reasonably anticipated." Sierra Club, 551 F.3d at 1025 (quotation omitted).

Sierra Club is the seminal case. In 1994, EPA adopted a rule that exempted major sources of air pollution from the Clean Air Act's emission standards during startups, shutdowns, and malfunctions (the "SSM exemption"). Id. at 1022. But the 1994 rule also required sources to develop an SSM plan in order to receive the benefit of the SSM exemption. Ibid. An SSM plan required "the source to demonstrate how it will do its reasonable best to maintain compliance with the standards, even during SSMs." Ibid. (quotation omitted). SSM plans were publicly available and were incorporated into the sources' permits under Title V of the Clean Air Act. Ibid.

In a series of rulemakings between 2002 and 2006, EPA substantially weakened the requirement that sources maintain and follow an SSM plan in order to benefit from the SSM exemption. It removed the requirement that a source's Title V permit incorporate its SSM plan; it stopped making SSM plans publicly available; and it ultimately retracted the requirement that sources implement their SSM plans during SSM periods. *Id.* at 1023.

The Sierra Club filed suit in 2007. But the Sierra Club did not challenge the changes to the SSM plan requirements that EPA had adopted in its 2002, 2003, and 2006 rulemakings. Instead, it challenged the legality of the SSM exemption itself. *Id.* at 1024. EPA had adopted that exception in 1994 and had not considered rescinding it in any of its rulemakings during the 2000s. Rather, those rulemakings had treated the SSM exemption as a given—in fact, they had strengthened it by weakening the SSM plan requirements. *See id.* at 1022–23.

The D.C. Circuit nonetheless held that the Sierra Club's challenge to the SSM exemption was timely. Even though EPA had not expressly reopened its decision to create a SSM exemption, it had constructively reopened that decision "by stripping out virtually all of the SSM plan requirements that it created to contain that exemption." *Id.* at 1025 (quotation omitted). Because EPA had allegedly abandoned these "necessary safeguards" limiting the SSM exemption, its rulemakings had "changed the calculus for petitioners in seeking judicial review and thereby constructively reopened consideration of the exemption." *Id.* at 1025–26 (quotation omitted).

Sierra Club thus establishes that an agency can constructively reopen a decision if it removes essential safeguards that had previously limited or contained the impact of that decision. In making this determination, the D.C. Circuit looks to the extent to which the agency has "alter[ed] th[e] regulatory

framework" and whether the agency has "work[ed] a change that [plaintiffs] could not have reasonably anticipated." *Nat'l Biodiesel Bd.*, 843 F.3d at 1017.

Under *Sierra Club* and its progeny, FDA's 2016 Major REMS Changes and 2021 Petition Denial seemingly reopened its 2000 Approval decision. Of course, FDA did not expressly reconsider its mifepristone approval. But it eliminated the "necessary safeguards," *Sierra Club*, 551 F.3d at 1025, that had accompanied and limited the impact of that approval for two decades. The in-person dispensing requirement, for example, was critical to FDA's initial approval of mifepristone in 2000, which relied on the in-person dispensing requirement to dismiss concerns about provider qualifications, improper use, illicit distribution, and detection of adverse events. *See* PI App. 519–23. And the in-person dispensing requirement was also the cornerstone of the REMS for mifepristone that FDA approved in 2011 and then relied on in its 2016 rejection of plaintiffs' 2002 Citizen Petition. *See* PI App. 578–82, 605, 608.

Thus FDA's elimination of the in-person distribution requirement—not to mention various other REMS—arguably worked a "sea change" in the legal framework governing mifepristone distribution that plaintiffs "could not have reasonably anticipated" and that "significantly alters the stakes of judicial review." *Nat'l Biodiesel Bd.*, 843 F.3d at 1017 (quotation omitted). That's because the in-person dispensing requirement was FDA's primary tool for ensuring the safe distribution and use of mifepristone, so plaintiffs arguably had little reason to anticipate this important change before 2021. FDA does not argue otherwise, appearing to concede that its 2021 announcement was a stark departure from previous regulatory approaches. And because this change eliminates a major safeguard against complications and adverse effects arising from improper mifepristone use, it can be said to "significantly alter[] the stakes of judicial review" for plaintiff doctors who treat patients with these complications. *Ibid.* (quotation omitted).

Even so, we ultimately hold at this early and emergency stage that these alterations didn't constructively reopen the 2000 Approval for review. That's because there's at least a colorable argument that plaintiffs "could have... reasonably anticipated" changes like those in 2016 and 2021 by dint of the statutorily defined supplemental application process and other similar revision mechanisms. NRDC v. EPA, 571 F.3d at 1266 (quotation omitted); see, e.g., 21 C.F.R. § 314.71(b). We also recognize that it's somewhat of a strain to say that the 2016 Major REMS Changes and 2021 Petition Denial (and related changes) altered the regulatory landscape to such a degree that the prior rule is only now "worth challenging" when it otherwise might "not have been." Sierra Club, 551 F.3d at 1025–26 (quotation omitted). After all, plaintiffs did challenge the 2000 Approval well before the 2016 and 2021 changes were even proposed. But again, plaintiffs could very well prevail on this reopening claim.

In the alternative, the district court held that plaintiffs were entitled to equitable tolling of the statute of limitations. FDA Add. 23–25. We are unpersuaded. "[A] litigant is entitled to equitable tolling of a statute of limitations only if the litigant establishes two elements: '(1) that he has been pursuing his rights diligently, and (2) that some extraordinary circumstance stood in his way and prevented timely filing.'" *Menominee Indian Tribe of Wis.* v. United States, 577 U.S. 250, 255 (2016) (quoting Holland v. Florida, 560 U.S. 631, 649 (2010)). Here, no "extraordinary circumstance" prevented plaintiffs from filing within six years of FDA's 2016 Petition Denial. The district court is of course correct that FDA took "13 years, 7 months, and 9 days" to render that March 2016 ruling, FDA Add. 24, but that delay had no impact on the length of the statute-of-limitations period or plaintiffs' capacity to challenge the 2016 Petition Denial.

C.

Next exhaustion. Stay applicants contend they are likely to succeed on the merits because plaintiffs failed to exhaust their claims before FDA. We disagree.

"As a general rule, claims not presented to the agency may not be made for the first time to a reviewing court." Wash. Ass'n for Television & Child. v. FCC, 712 F.2d 677, 680 (D.C. Cir. 1983); cf. United States v. L.A. Tucker Truck Lines, 344 U.S. 33, 37 (1952). For challenges to FDA actions, the general administrative exhaustion requirement is codified at 21 C.F.R. § 10.45(b). Section 10.45(b) states that a "request that the [FDA] Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a)." See id. § 10.25(a) ("An interested person may petition the [FDA] Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.").

No one disputes that every argument the plaintiffs raised in their 2019 Citizen Petition is exhausted. That includes all of plaintiffs' challenges to the 2016 Major REMS Changes and everything fairly embraced by those challenges. For example, the 2019 Citizen Petition argued explicitly that FDA should "[c]ontinue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals." FDA Add. 193, 209–16. When FDA rejected that request in the 2021 Petition Denial, it expressly reaffirmed its commitment to mail-order abortion drugs. As such, plaintiffs have properly exhausted their challenge to FDA's by-mail distribution regime by raising it in the 2019 Citizen Petition.

Even if plaintiffs failed to exhaust their claims, courts retain "discretion to waive exhaustion" where one of the "traditionally

recognized" exceptions applies. Wash. Ass'n for Television & Child., 712 F.2d at 681–82. Two exceptions are relevant here: futility and administrative abuse of process.

Start with futility. Plaintiffs need not exhaust claims where they can demonstrate "the futility or inadequacy of administrative review." *Gardner v. Sch. Bd. Caddo. Par.*, 958 F.2d 108, 112 (5th Cir. 1992); *see also Honig v. Doe*, 484 U.S. 305, 327 (1988). The futility exception applies when exhaustion would be "clearly useless" and "it is certain [a] claim will be denied." *Tesoro Refin. & Mktg. Co. v. FERC*, 552 F.3d 868, 874 (D.C. Cir. 2009) (quotation omitted); *see also Carr v. Saul*, 141 S. Ct. 1352, 1361 (2021) ("[T]his Court has consistently recognized a futility exception to exhaustion requirements.").

Given FDA's 2016 Petition Denial and its 2021 Petition Denial, it would have been futile for plaintiffs to include a challenge to the 2000 Approval in their 2019 Citizen Petition. FDA rejected this exact challenge in its 2016 Petition Denial. So it would have been "clearly useless" to raise the precise challenge again in the 2019 Citizen Petition. Further, this exact reasoning applies with equal force to plaintiffs' challenge to the 2019 Generic Approval because it's entirely dependent on the underlying 2000 Approval. Thus, plaintiffs' challenges to the 2000 Approval and the 2019 Generic Approval are not barred by exhaustion.

Next, administrative abuse of process. It's well-established that where an agency fails to follow its own regulations, exhaustion may not be required. See Way of Life Television Network, Inc. v. FCC, 593 F.2d 1356, 1359-60 (D.C. Cir. 1979); see also Wash. Ass'n for Television & Child., 712 F.2d at 681. That's especially true "where the obvious result would be a plain miscarriage of justice." Hormel v. Helvering, 312 U.S. 552, 558 (1941). Here, FDA was required by its own regulations to respond to citizen petitions within 180

days. See 21 C.F.R. § 10.30(e)(2). Instead of timely responding, FDA responded to plaintiffs' first petition fourteen years after it was filed. And it responded to the second petition over two years after it was filed. FDA plainly and repeatedly refused to follow its own regulations here. Even assuming any of plaintiffs' challenges were unexhausted and that it wasn't futile to raise them before FDA, FDA's repeated failure to follow its own regulations indicates that the district court did not abuse its "discretion to waive exhaustion." Wash. Ass'n for Television & Child., 712 F.2d at 681.

D.

As applicants recognize, FDA's actions are constrained by the APA's arbitrary-and-capricious standard. See 5 U.S.C. § 706(2)(A). Under that standard, "the agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (quotation omitted); see also Sw. Elec. Power Co. v. EPA, 920 F.3d 999, 1013 (5th Cir. 2019) (judicial review of agency action "is not toothless"). We must "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." State Farm, 463 U.S. at 43 (quotation omitted). An agency's action is "arbitrary and capricious" if it "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Ibid.

When an agency acts, it must "reasonably consider[] the relevant issues and reasonably explain[]" its actions. FCC v. Prometheus Radio Project, 141 S. Ct. 1150, 1158 (2021); see also ibid. ("The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably

explained."); *Michigan v. EPA*, 576 U.S. 743, 750, 752 (2015) ("[A]gency action is lawful only if it rests on a consideration of the relevant factors" and "important aspect[s] of the problem." (quotation omitted)). Of course, we cannot "substitute" our "own policy judgment for that of the agency." *Prometheus*, 141 S. Ct. at 1158. We nonetheless must still carefully ensure that "the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Ibid.* The upshot is that we "must set aside any action premised on reasoning that fails to account for 'relevant factors' or evinces 'a clear error of judgment." *Univ. of Tex. M.D. Anderson Cancer Ctr. v. HHS*, 985 F.3d 472, 475 (5th Cir. 2021) (quoting *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 378 (1989)).

Here, applicants have failed to carry their burden at this preliminary stage to show that FDA's actions⁵ were not arbitrary and capricious. We have two principal concerns in that regard. First, FDA failed to "examine the relevant data" when it made the 2016 Major REMS changes. *State Farm*, 463 U.S. at 43. That's because FDA eliminated REMS safeguards based on studies that *included those very safeguards*. FDA Add. 59, 122–23, 171. Imagine that an agency compiles studies about how cars perform when they have passive restraint systems, like automatic seatbelts. *See State Farm*, 463 U.S. at 34–36. For nearly a decade, the agency collects those studies and continues studying how cars perform with passive safety measures. Then one day the agency changes its mind and *eliminates* passive safety measures based only on existing data of how cars perform *with* passive safety measures. *Cf. id.* at 47–

⁵ Here we limit our discussion to FDA's decisions in the 2016 Major REMS Changes and its subsequent agency actions. As described above in Part III.B, it appears at this preliminary juncture that plaintiffs' challenges to the 2000 Approval and 2016 Petition Denial are untimely.

49. That was obviously arbitrary and capricious in *State Farm*. And so too here. The fact that mifepristone might be safe when used with the 2000 Approval's REMS (a question studied by FDA) says nothing about whether FDA can eliminate those REMS (a question not studied by FDA).

True, FDA studied the safety consequences of eliminating one or two of the 2000 Approval's REMS in *isolation*. But it relied on zero studies that evaluated the safety-and-effectiveness consequences of the 2016 Major REMS Changes as a whole. This deficiency shows that FDA failed to consider "an important aspect of the problem" when it made the 2016 Major REMS Changes. *Michigan v. EPA*, 576 U.S. at 752 (quotation omitted).

Second, the 2016 Major REMS Changes eliminated the requirement that non-fatal adverse events must be reported to FDA. After eliminating that adverse-event reporting requirement, FDA turned around in 2021 and declared the absence of non-fatal adverse-event reports means mifepristone is "safe." See, e.g., FDA Add. 861–76 (explaining that FDA's FAERS database, which collates data on adverse events, indicated that the 2016 Major REMS Changes hadn't raised "any new safety concerns"). This ostrich's-head-in-the-sand approach is deeply troubling—especially on a record that, according to applicants' own documents, necessitates a REMS program, a "Patient Agreement Form," and a "Black Box" warning. See supra Part III.A. And it suggests FDA's actions are well "outside the zone of reasonableness." Prometheus, 141 S. Ct. at 1160. It's unreasonable for an agency to eliminate a reporting requirement for a thing and then use the resulting absence of data to support its decision.

These actions make it unlikely that plaintiffs' arbitrary-and-capricious challenges will fail on the merits, at least as far as they challenge FDA's decisions including and following the 2016 Major REMS Changes.

IV.

Beyond likelihood of success on the merits, we also must consider the other three factors for granting a stay. Those are "[A] whether the applicant will be irreparably injured absent a stay; [B] whether issuance of the stay will substantially injure the other parties interested in the proceeding; and [C] where the public interest lies." *Nken*, 556 U.S. at 434 (quotation omitted). We address each in turn. And we (D) discuss how the Comstock Act, 18 U.S.C. §§ 1461, 1462 affects the stay inquiry. Outside of the 2000 Approval, we find that the applicants fail to make a strong showing on any of these factors for a stay.

A.

Of the remaining three factors, irreparable injury matters most. See Nken, 556 U.S. at 434. FDA argues that the plaintiffs fail to show irreparable injury. But the irreparable injury factor asks whether "the [stay] applicant will be irreparably injured" absent a stay, not whether the plaintiff would be irreparably injured absent an injunction. Ibid. (emphasis added) (quotation omitted). Similarly, FDA's assertion that the district court's injunction will harm pregnant women or other members of the public does not speak to the irreparable injury factor (although it may speak to other factors), because those persons are not stay applicants in this case.

Since FDA does not articulate any irreparable harm that *FDA* will suffer absent a stay, it makes no showing on this "critical" prong. *Ibid*. We may not need to address the merits of the applicants' stay request any further, because failure to show irreparable injury often "decides the [stay] application." *Whalen v. Roe*, 423 U.S. 1313, 1318 (1975) (Marshall, J., in chambers).

Danco by contrast does claim it will suffer irreparable injury, albeit in just one paragraph. Danco notes that mifepristone is its sole product and

argues that it may have to shut down absent relief. We have held that catastrophic financial losses "may be sufficient to show irreparable injury." Wages & White Lion Investments, LLC v. FDA, 16 F.4th 1130, 1142 (5th Cir. 2021) (emphasis added) (quotation omitted). Of course, irreparable injury alone does not entitle Danco to a stay. See Virginian Ry. Co., 272 U.S. at 672.

And even if it did, neither FDA nor Danco articulates why this, or any other, injury would require a stay of *all* of the district court's order, rather than only part. Recall that we may narrowly "tailor a stay" to impact "only some portion of the proceeding." *Int'l Refugee Assistance Project*, 137 S. Ct. at 2087 (quotation omitted). The applicants' arguments suggest, at best, that they require relief only from the district court's treatment of the 2000 Approval. They make no argument as to why the district court's treatment of the 2016 Major REMS Changes and later FDA activity irreparably harms anyone.

Applicants' forfeiture of this contention is understandable because the world operated under the 2000 Approval for sixteen years, apparently without problems. And neither applicant contends that it'll be irreparably injured without a stay so long as the 2000 Approval and its associated REMS remain in effect. Thus, the irreparable injury factor counsels against a stay.

B.

The next *Nken* factor asks whether "issuance of the stay will substantially injure the other parties interested in the proceeding." 556 U.S. at 434 (quoting *Hilton*, 481 U.S. at 776); see also Ala. Ass'n of Realtors, 141 S. Ct. at 2487 (same); Planned Parenthood v. Abbott, 134 S. Ct. 506, 506–08 (2013) (mem.) (opinions of seven Justices using the same standard). This language again focuses on harm from the stay, not the injunction. Cf. Whole Woman's Health, 141 S. Ct. at 2495 (using less specific "balance of the equities" language). To succeed on this prong, applicants must show that the

requested stay will not harm the opposing appellees or other interested parties.

Applicants discuss at length their view that *the district court's order* might harm various persons, but mostly decline to address the apposite question, which is why *the requested stay* would not harm relevant persons. What points the applicants do make on this relevant question distill down to two arguments.

First, applicants briefly argue that the injuries the plaintiffs would suffer from a stay are speculative or minimal. But we have already addressed why plaintiffs' injuries are non-speculative. *See supra* Part III.A. We have also addressed the specific risks impacting women and the plaintiffs that stem from the 2016 Major REMS Changes and other post-2016 FDA decisions that the district court enjoined. *See supra* Part III.A, D. The applicants' abbreviated argument focuses on consequences flowing from the district court's treatment of the 2000 Approval and largely ignores plaintiffs' alternative arguments regarding the 2016 Major REMS Changes and what followed.

Second, the applicants argue that the plaintiffs' failure to bring litigation sooner undercuts any contention that they would be harmed from a stay. That contention is untenable given FDA's *fourteen-year delay* in adjudicating the 2002 Citizen Petition. But, even setting aside FDA's own delays, the applicants do not explain why the plaintiffs' alleged procrastination warrants a stay of the entirety of the district court's order, rather than just the portion of the order impacted by long litigation delay (the 2000 Approval).

To the extent applicants make any showing that the third *Nken* factor favors a stay, they do so only with respect to the 2000 Approval and do not address plaintiffs' alternative arguments.

C.

The last *Nken* factor asks "where the public interest lies." 556 U.S. at 434 (quotation omitted). The stay applicants make three principal arguments.

First, the applicants argue that "procedural irregularity" in the court below favors relief. But the applicants do not explain why any specific alleged irregularity necessarily speaks to public (versus their own private) interest. Even if we assume away that problem, it is not clear to us, on our accelerated review, that any litigation below was irregular. And even if we assume, which we do not, that the district court or the plaintiffs departed from acceptable procedure, it's unclear on this record that applicants have embraced "the principles of equity and righteous dealing" in the twenty-one years since the filing of the 2002 Citizen Petition. *Binh Hoa Le v. Exeter Fin. Corp.*, 990 F.3d 410, 416 (5th Cir. 2021) (quotation omitted) (noting that a party's own imperfect conduct can prejudice their request for equitable relief).

Second, Danco argues that avoidance of "judicial conflict" warrants a stay given the order of an out-of-circuit district court. Comity between federal courts is a cognizable interest. *See Def. Distrib. v. Platkin*, 55 F.4th 486, 495–96 (5th Cir. 2022). We have every respect for fellow federal courts. But we cannot embrace an argument that would, in effect, allow the decision of an out-of-circuit district court to impel us towards "extraordinary" relief that would be otherwise inappropriate. *Williams*, 442 U.S. at 1311 (quotation omitted).

Third, the stay applicants warn us of significant public consequences should the district court's order result in the withdrawal of mifepristone from the market. These consequences, the applicants say, include injury to pregnant women, to public healthcare systems, and to the sense of order that governs FDA drug approvals. But these concerns center on the district

court's removal of mifepristone from the market. The applicants make no arguments as to why the 2016 Major REMS Changes, the 2019 Generic Approval, or the 2021 and 2023 Mail Order Decisions are similarly critical to the public even though they were on notice of plaintiffs' alternative requests for relief. And it would be difficult for applicants to argue that the 2016 Major REMS Changes and subsequent FDA activity were so critical to the public given that the Nation operated—and mifepristone was administered to millions of women—without them for sixteen years following the 2000 Approval.

The applicants have made some showing that the public interest warrants equitable relief from the district court's treatment of the 2000 Approval. Motivated in part by the accelerated posture of our review, we credit their showing.

D.

The parties vehemently dispute how their competing interpretations of the Comstock Act of 1873 might impact the validity of the district court's order. The Comstock Act prohibits the carriage in interstate commerce of "any drug, medicine, article, or thing designed, adapted or intended for producing abortion." 18 U.S.C. § 1462. It similarly prohibits the mailing of any "article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion." *Id.* § 1461.

Both statutory provisions specify a *mens rea* of "knowingly." *Id.* §§ 1461–62. The plain text does not require that a user of the mails or common interstate carriage intend that an abortion actually occur. Rather, a user of those shipping channels violates the plain text merely by knowingly making use of the mail for a prohibited abortion item.

The applicants' principal defense against the Comstock Act is that FDA was not required to consider it. After all, say the applicants, 21 U.S.C. §§ 355 and 355-1 guide FDA's discretion over drug approval and REMS, and those statutes do not explicitly require consideration of other statutes like 14 U.S.C. § 1462.

Even assuming that's true, however, the Comstock Act nevertheless undermines applicants' showing on the final three *Nken* factors. For example, if the Comstock Act is construed in-line with its literal terms, then Danco cannot say it is irreparably harmed by the district court's order, because Danco has no interest in continuing to violate the law, which (under a plain view of the Act) it does every time it ships mifepristone. For further example, if the Comstock Act is strictly understood, then applicants may lose the public interest prong entirely, because there is no public interest in the perpetuation of illegality. *See Louisiana v. Biden*, 55 F.4th 1017, 1035 (5th Cir. 2022).

The applicants raise other defenses. For example, they argue that the Food and Drug Administration Amendments Act, Pub. L. No. 110-85, 121 Stat. 823 (2007) ("FDAAA") sub silentio repealed the Comstock Act, at least where mifepristone is concerned. That's because the FDAAA in 2007 created a statutory framework governing REMS and drugs with then-existing distribution restrictions. See id. § 909(b). Mifepristone was one such drug. So, say applicants, the FDAAA acted to legalize shipment of mifepristone, regardless of what the Comstock Act might say. But "repeals by implication are not favored." Maine Cmty. Health Options v. United States, 140 S. Ct. 1308, 1323 (2020) (quotation omitted). We regard each of Congress's statutes as effective unless either "intention to repeal" one of them is "clear and manifest" or the two laws are "irreconcilable." Ibid. (quotation omitted). Section 909(b) did not expressly legalize mifepristone; agency action (not statute) did that. Section 909(b)'s brief text makes no mention of

mifepristone at all. So, there is no "irreconcilable" conflict. And we hesitate to find "clear and manifest" intention to repeal a 150-year-old statute that Congress has otherwise repeatedly declined to alter in the far reaches of a single section of the cavernous FDAAA.

Failing all else, the applicants argue that the Comstock Act does not mean what it says it means. Or rather, that judicial gloss and lax enforcement over the past century act to graft relevant exceptions onto it. The applicants rely on a memo authored by the Office of Legal Counsel to press this position. See FDA Add. 258–78. That memo's thorough exploration of this topic notes that a variety of aging out-of-circuit opinions and a single footnote within one Supreme Court dissent favor the applicants' position. FDA Add. 262–68.

The speed of our review does not permit conclusive exploration of this topic. To the extent the Comstock Act introduces uncertainty into the ultimate merits of the case, that uncertainty favors the plaintiffs because the applicants bear the burden of winning a stay. See Landis, 299 U.S. at 255. Since plaintiffs already prevail on most Nken factors concerning most of the agency items effectively enjoined by the district court's order, we need not definitively interpret the Comstock Act to resolve this stay application.

* * *

As the stay applicants, defendants bear the burden of showing why "extraordinary circumstances" demand that we exercise discretion in their favor. To the extent the defendants make any such showing, they do so *only* with respect to the 2000 Approval—*not* the plaintiffs' alternative arguments challenging FDA's 2016 Major REMS Changes and all subsequent actions. Our decision to grant partial relief does not reflect our view on any merits question. The defendants' motions to stay the district court's order are GRANTED IN PART and DENIED IN PART. The appeal is EXPEDITED to the next available Oral Argument Calendar.

ALITO, J., dissenting

SUPREME COURT OF THE UNITED STATES

No. 22A901

DANCO LABORATORIES, LLC v. ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

ON APPLICATION FOR STAY

No. 22A902

FOOD AND DRUG ADMINISTRATION, ET AL. v. ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

ON APPLICATION FOR STAY

[April 21, 2023]

The applications for stays presented to JUSTICE ALITO and by him referred to the Court are granted. The April 7, 2023 order of the United States District Court for the Northern District of Texas, case No. 2:22–cv–223, is stayed pending disposition of the appeal in the United States Court of Appeals for the Fifth Circuit and disposition of a petition for a writ of certiorari, if such a writ is timely sought. Should certiorari be denied, this stay shall terminate automatically. In the event certiorari is granted, the stay shall terminate upon the sending down of the judgment of this Court.

JUSTICE THOMAS would deny the applications for stays.

JUSTICE ALITO, dissenting from grant of applications for stays.

In recent cases, this Court has been lambasted for staying a District Court order "based on the scanty review this Court gives matters on its shadow docket," *Merrill* v. *Milligan*, 595 U. S. ____, ___ (2022) (KAGAN, J., dissenting) (slip

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op., at 2). In another, we were criticized for ruling on a stay application while "barely bother[ing] to explain [our] conclusion," a disposition that was labeled as "emblematic of too much of this Court's shadow-docket decisionmaking which every day becomes more unreasoned." Woman's Health v. Jackson, 594 U.S. ____, ____ (KAGAN, J., dissenting from denial of application for injunctive relief) (slip op., at 1-2). And in a third case in which a stay was granted, we were condemned for not exhibiting the "restraint" that was supposedly exercised in the past and for not "resisting" the Government's effort to "shortcut" normal process. Barr v. East Bay Sanctuary Covenant, 588 U. S. ____, ___ (2019) (SOTOMAYOR, J., dissenting) (slip op., at 5). Cf. Does 1-3 v. Mills, 595 U.S. ___, ___ (2021) (BARRETT, J., concurring in denial of application for injunctive relief) (slip op., at 1) (warning that the Court should not act "on a short fuse without benefit of full briefing and oral argument" in a case that is "first to address the questions presented").

I did not agree with these criticisms at the time, but if they were warranted in the cases in which they were made, they are emphatically true here. As narrowed by the Court of Appeals, the stay that would apply if we failed to broaden it would not remove mifepristone from the market. It would simply restore the circumstances that existed (and that the Government defended) from 2000 to 2016 under three Presidential administrations. In addition, because the applicants' Fifth Circuit appeal has been put on a fast track, with oral argument scheduled to take place in 26 days, there is reason to believe that they would get the relief they now seek—from either the Court of Appeals or this Court—in the near future if their arguments on the merits are persuasive.

At present, the applicants are not entitled to a stay because they have not shown that they are likely to suffer irreparable harm in the interim. The applicants claim that

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regulatory "chaos" would occur due to an alleged conflict between the relief awarded in these cases and the relief provided by a decision of the United States District Court for the Eastern District of Washington. It is not clear that there actually is a conflict because the relief in these cases is a stay, not an injunction, but even if there is a conflict, that should not be given any weight. Our granting of a stay of a lower-court decision is an equitable remedy. It should not be given if the moving party has not acted equitably, and that is the situation here. The Food and Drug Administration (FDA) has engaged in what has become the practice of "leverag[ing]" district court injunctions "as a basis" for implementing a desired policy while evading both necessary agency procedures and judicial review. Arizona v. City and County of San Francisco, 596 U.S. ____, ___ (2022) (ROBERTS, C. J., concurring) (slip op., at 2).

The Washington District Court enjoined the FDA from altering its current practice regarding mifepristone—something that the FDA had never hinted it was contemplating. The FDA did not appeal that appealable order, and when seven States that might take such an appeal asked to intervene, the FDA opposed their request. This series of events laid the foundation for the Government's regulatory "chaos" argument.

Once this argument is put aside, the applicants' argument on irreparable harm is largely reduced to the claim that Danco could not continue to market mifepristone because the drug would be mislabeled and that distribution could not resume until Danco jumped through a series of regulatory steps that would be largely perfunctory under present circumstances. That would not take place, however, unless the FDA elected to use its enforcement discretion to stop Danco, and the applicants' papers do not provide any reason to believe the FDA would make that choice. The FDA has previously invoked enforcement discretion to permit the distribution of mifepristone in a way that the

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regulations then in force prohibited, and here, the Government has not dispelled legitimate doubts that it would even obey an unfavorable order in these cases, much less that it would choose to take enforcement actions to which it has strong objections.

For these reasons, I would deny the stay applications. Contrary to the impression that may be held by many, that disposition would not express any view on the merits of the question whether the FDA acted lawfully in any of its actions regarding mifepristone. Rather, it would simply refuse to take a step that has not been shown as necessary to avoid the threat of any real harm during the presumably short period at issue.

ORDER GRANTING IN PART PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION ~ 1

DEPARTMENT OF HEALTH AND

HUMAN SERVICES, and XAVIER

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BECERRA, in his official capacity as Secretary of the Department of Health and Human Services,

Defendants.

BEFORE THE COURT are Plaintiffs' Motion for Preliminary Injunction (ECF No. 3), Third Parties' Unopposed Motion for Leave to File Amicus Curiae Brief (ECF No. 52), and Third Parties' Unopposed Motion for Leave to File Amicus Brief (ECF No. 69). The Motion for Preliminary Injunction was submitted for consideration with oral argument on March 28, 2023. Kristin Beneski, Colleen M. Melody, and Noah G. Purcell appeared on behalf of Plaintiffs. Noah T. Katzen, Aravind Sreenath, and Molly Smith appeared on behalf of Defendants. The Court has reviewed the record and files herein, and is fully informed. For the reasons discussed below, Plaintiffs' Motion for Preliminary Injunction (ECF No. 3) is granted in part, Third Parties' Unopposed Motion for Leave to File Amicus Curiae Brief (ECF No. 52) is denied, and Third Parties' Unopposed Motion for Leave to File Amicus Brief (ECF No. 69) is denied.

BACKGROUND

This case concerns federal regulation of mifepristone used in connection with the termination of early pregnancy. ECF No. 35. Plaintiffs seek a preliminary injunction, asking this Court to "affirm[] "FDA's original conclusion that mifepristone is safe and effective, preserv[e] the status quo by enjoining any

actions by Defendants to remove this critical drug from the market, and enjoin[] the unnecessary and burdensome January 2023 restrictions." ECF No. 3 at 5. The parties timely filed their respective response and reply. ECF Nos. 51, 60. The following facts are generally undisputed for purposes of resolving the instant motion.

In 1992, Subpart H regulations authorized the Food and Drug

Administration ("FDA") to require conditions "needed to assure safe use" for
certain drugs. Final Rule, 57 Fed. Reg. 58,942, 58,958 (December 11, 1992)
(codified at 21 C.FR. § 314.520). In September 2000, FDA approved
mifepristone¹ under Subpart H, concluding that mifepristone is safe and effective
for medical termination of intrauterine pregnancy through 49 days' gestation when
used in a regimen with the already-approved drug, misoprostol. ECF No. 35 at 21,
¶ 85. FDA's restrictions on mifepristone included requiring (1) an in-person
dispensing requirement where the drug could only be dispensed in a hospital,
clinic, or medical office, by or under the supervision of a certified provider who at
the time could only be a physician, (2) providers attest to their clinical abilities in a

As referenced herein, mifepristone is the drug used for early termination of pregnancy, such as Mifeprex and the generic drug. This Order does not impact mifepristone as used in Korlym, a drug used to treat Cushing's syndrome.

signed form kept on file by the manufacturer, and agree to comply with reporting and other REMS requirements, and (3) prescribers and patients review and sign a form with information about the regimen and risks and that the prescriber provide copies to the patient and patient's medical record. *Id.* at 24, ¶ 87.

From 1992 to February 2002, seven New Drug Applications ("NDA"), including Mifeprex, were approved subject to these conditions, in contrast to the 961 NDAs with no additional restrictions from January 1993 to September 2005. ECF No. 35 at 24–25, ¶ 88.

The Food and Drug Administration Amendments Act of 2007 effectively replaced Subpart H with the REMS statute codified at 21 U.S.C. § 355-1. Pub. L. No. 110-85, tit. IX, § 901. All drugs previously approved under Subpart H, including Mifeprex, were deemed to have a REMS in place. Pub. L. No. 110-85, tit. IX, § 909(b). Under the Federal Food, Drug and Cosmetic Act ("FDCA"), a new drug cannot be marketed and prescribed until it undergoes a rigorous approval process to determine that it is safe and effective. 21 U.S.C. § 355.

In 2011, FDA issued a new REMS for Mifeprex incorporating the same restrictions under which the drug was approved eleven years earlier. *Id.*, ¶ 90; ECF No. 51-2. In 2013, FDA reviewed the existing REMS and reaffirmed the restrictions in place. ECF No. 35 at 25, ¶ 91.

In 2015, Mifeprex's manufacturer submitted a supplemental NDA proposing to update the label to reflect evidence-based practices across the country – namely, the use of 200 mg of mifepristone instead of 600 mg. *Id.*, ¶ 92. In July 2015, the manufacturer submitted its REMS assessment, proposing minor modifications. *Id.* This submission prompted a review of the Mifeprex label and REMS by FDA. *Id.* at 26, ¶ 93. As part of the review, FDA received letters from more than 40 medical experts, researches, advocacy groups, and professional associations who asked, *inter alia*, that the REMS be eliminated in their entirety. *Id.* One letter asked FDA to "[e]liminate the REMS and ETASU (Elements to Assure Safe Use), including eliminating the certification and patient agreement requirements. *Id.* at 27, ¶ 95.

In 2016, FDA found "no new safety concerns have arisen in recent years, and that the known serious risks occur rarely," and that "[g]iven that the number of ... adverse events appear to be stable or decreased over time, it is likely that ... serious adverse events will remain acceptably low." *Id.* at 30, ¶ 100. Following this review, FDA changed Mifeprex's indication, labeling, and REMS, including increasing the gestational age limit from 49 to 70 days, reducing the number of required in-person clinic visits to one, finding at-home administration of misoprostol safe, finding no significant differences in outcomes based on whether patients had a follow-up phone call or in person or based on the timing of those appointments, and allowing a broader set of healthcare providers to prescribe

mifepristone. Id., ¶ 101. However, FDA still required that mifepristone be administered in a clinic setting. Id.

In 2019, FDA approved a different manufacturer's abbreviated NDA for a generic version of mifepristone and established the Mifepristone REMS Program, which covered both Mifeprex and the generic drug. *Id.* at 32, ¶ 103; ECF No. 51-3. In May 2020, American College of Obstetricians and Gynecologists ("ACOG") sued FDA, challenging the Mifepristone REMS Program's in-person dispensing requirement in light of the COVID-19 pandemic. ECF No. 35, ¶ 104. In that case, the district court temporarily enjoined FDA from enforcing the in-person dispensation requirements under the REMS in light of the COVID-19 pandemic. *American College of Obstetricians and Gynecologists v. United States Food and Drug Administration*, 47 2F. Supp. 3d 183 (D. Md. 2020).

In April 2021, FDA suspended the in-person dispensing requirement during the COVID-19 public health emergency because, during the six-month period in which the in-person dispensing requirement had been enjoined, the availability of mifepristone by mail showed no increases in serious patient safety concerns. *Id.*, ¶ 105.

On May 7, 2021, FDA announced it would review whether the Mifepristone REMS Program should be modified. ECF No. 51-4. FDA reviewed materials between March 29, 2016 and July 26, 2021, as well as publications found on

PubMed and Embase and those provided by "advocacy groups, individuals, plaintiffs in *Chelius v. Becerra*, 1:17-493-JAO-RT (D. Haw.), application holders, and healthcare providers and researchers. *Id.* at 10–11.

On December 16, 2021, FDA announced its conclusions regarding the Mifepristone REMS Program. ECF No. 51-5. On January 3, 2023, FDA accepted these conclusions by approving the supplemental applications proposing conforming modifications. ECF Nos. 51-8; 51-11. The 2023 REMS removed the in-person dispensing requirement and added a pharmacy-certification requirement. ECF Nos. 51-4, 51-5. The FDA maintained the Prescriber and Patient Agreement Form requirements. *Id*.

DISCUSSION

I. Preliminary Injunction Standard

Plaintiffs, on behalf of themselves and as *parens patriae* in protecting the health and well-being of its residents, moves for a preliminary injunction "affirming FDA's original conclusion that mifepristone is safe and effective, preserving the status quo by enjoining any actions by Defendants to remove this critical drug from the market, and enjoining the unnecessary and burdensome January 2023 restrictions." *See* ECF Nos. 3 at 5; 35.

Pursuant to Federal Rule of Civil Procedure 65, the Court may grant preliminary injunctive relief in order to prevent "immediate and irreparable

injury." Fed. R. Civ. P. 65(b)(1)(A). To obtain this relief, a plaintiff must demonstrate: (1) a likelihood of success on the merits; (2) a likelihood of irreparable injury in the absence of preliminary relief; (3) that a balancing of the hardships weighs in plaintiff's favor; and (4) that a preliminary injunction will advance the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *M.R. v. Dreyfus*, 697 F.3d 706, 725 (9th Cir. 2012). Under the *Winter* test, a plaintiff must satisfy each element for injunctive relief.

Alternatively, the Ninth Circuit also permits a "sliding scale" approach under which an injunction may be issued if there are "serious questions going to the merits" and "the balance of hardships tips sharply in the plaintiff's favor," assuming the plaintiff also satisfies the two other *Winter* factors. *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir. 2011) ("[A] stronger showing of one element may offset a weaker showing of another."); *see also Farris v. Seabrook*, 677 F.3d 858, 864 (9th Cir. 2012) ("We have also articulated an alternate formulation of the *Winter* test, under which serious questions going to the merits and a balance of hardships that tips sharply towards the plaintiff can support issuance of a preliminary injunction, so long as the plaintiff also shows that there is a likelihood of irreparable injury and that the injunction is in the public interest." (internal quotation marks and citation omitted)).

A preliminary injunction can either be prohibitory or mandatory. *Marlyn Nutraceuticals, Inc. v. Mucos Pharma GmbH & Co.*, 571 F.3d 873, 878 (9th Cir. 2009). A prohibitory injunction preserves the status quo which is the "last, uncontested status which preceded the pending controversy." *Id.* at 879. A mandatory injunction "orders a responsible party to take action." *Id.* at 878. Mandatory injunctions are disfavored and require a higher showing that the "facts and law clearly favor the moving party." *Garcia v. Google*, 786 F.3d 733, 740 (9th Cir. 2015).

Plaintiffs contend they are seeking a prohibitory injunction to maintain the "status quo." ECF Nos. 3, 78. Plaintiffs seek an "order enjoining Defendants from doing two things: (1) enforcing the 2023 REMS, and (2) changing the status quo to make mifepristone less available in the Plaintiff States." ECF No. 60 at 19. However, when addressing Defendants' argument that the 2023 REMS is less restrictive than any prior REMS, Plaintiffs contend they "seek to enjoin the application of *any* REMS, such that mifepristone can be prescribed just like the 20,000+ other drugs that don't have one." *Id.* at 10. At oral argument, Plaintiffs maintain they seek a prohibitory injunction.

The status quo, i.e., the last uncontested status preceding the pending controversy, were the REMS in place prior to the 2023 REMS. Considering the

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conflicting requests, the Court will apply the prohibitory injunction standard to the extent Plaintiffs seek to maintain the status quo.

A. Likelihood of Success on the Merits

Plaintiffs assert they are likely to succeed on the success of the merits of the claim that the 2023 REMS violated the Administrative Procedures Act ("APA"). ECF No. 3 at 16–19. Defendants disagree and also contend that Plaintiffs lack standing and have not exhausted their administrative remedies. ECF No. 51.

1. Standing

Plaintiffs brings suit on behalf of themselves and as *parens patriae* in protecting the health and well-being of its residents. *See* ECF No. 35. Defendants argue Plaintiffs lack standing where the federal government is the ultimate *parens patriae* and the alleged economic interests are insufficient to establish standing. ECF No. 51.

The APA provides a cause of action to any "person ... adversely affected or aggrieved by agency action." 5 U.S.C. § 702. A state qualifies as a "person" within the meaning of the APA. See Maryland Dep't of Human Res. v. Dep't of Health & Human Servs., 763 F.2d 1441, 1445 n.1 (D.C. Cir. 1985). The APA allows a person to challenge agency action under various statutes. See Block v. Cmty. Nutrition Inst., 467 U.S. 340, 345 (1984).

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a. Parens Patriae Suit

A parens patriae lawsuit allows a state to sue in a representative capacity on behalf of its citizens' interests. Gov't of Manitoba v. Bernhardt, 923 F.3d 173, 178 (D.C. Cir. 2019). In order to establish standing beyond Article III's minimum, the State must assert a quasi-sovereign interest "apart from the interests of particular private parties." Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez, 458 U.S. 592, 607 (1982). A state has a quasi-sovereign interest "in the health and well-being – both physical and economic – of its residents" and "in not being discriminatorily denied its rightful status within the federal system." Id. at 607. Courts look to "whether the injury is one that the State, if it could, would likely attempt to address through its sovereign lawmaking powers." Id.

Under the *Mellon* bar, a state lacks standing as *parens patriae* to bring an action against the federal government. *Massachusetts v. Mellon*, 262 U.S. 447, 485–86 (1923). However, "courts must dispense with [the *Mellon* bar] if Congress so provides." *Maryland People's Couns. v. FERC*, 760 F.2d 318, 321 (D.C. Cir. 1985). "The cases on the standing of states to sue the federal government seem to depend on the kind of claim that the state advances. The decisions ... are hard to reconcile." *Arizona State Legislature v. Arizona Indep. Redistricting Comm'n*, 576 U.S. 787, 802, n.10 (2015).

1 Courts have determined that the APA alone does not demonstrate 2 congressional intent to authorize a state to sue the federal government as parens 3 patriae. See Bernhardt, 923 F.3d at 181; Am. Fed'n of Tchrs. v. Cardona, No. 4 5:20-CV-00455-EJD, 2021 WL 4461187, at *5 (N.D. Cal. Sept. 29, 2021). 5 However, states are not necessarily precluded from bringing a parens patriae suit 6 against the federal government, including where the underlying statute forming the 7 basis for the APA action authorizes a parens patriae suit. See New York v. United 8 States Dep't of Lab., 477 F. Supp. 3d 1, 9, n.6 (S.D.N.Y. 2020); New York v. 9 Biden, No. 20-CV-2340(EGS), 2022 WL 5241880, at *7 (D.D.C. Oct. 6, 2022) (allowing parens patriae suit against federal government where "Plaintiffs' efforts 10 11 to mitigate the spread of COVID-19 are aimed at protecting the public health of 12 their respective jurisdictions as a whole."); Louisiana v. Becerra, No. 3:21-CV-13 04370, 2022 WL 4370448, at *5 (W.D. La. Sept. 21, 2022) (finding states have 14 parens patriae and/or quasi-sovereign interest in APA claims on behalf of 15 citizens). 16 17 18

Regardless of whether Plaintiffs have standing to assert claims on behalf of its citizens under the APA in this case, Plaintiffs allege direct injuries sufficient to confer standing. Therefore, the Court declines to resolve the *parens patriae* issue. //

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b. Direct Suit

In a direct suit where a state seeks redress for its own injuries, the state must meet Article III's minimum requirements. *Bernhardt*, 923 F.3d at 178. A plaintiff "must allege that they have suffered, or will imminently suffer, a 'concrete and particularized' injury in fact." *City & Cnty. of San Francisco v. United States Citizenship & Immigr. Servs.*, 981 F.3d 742, 754 (9th Cir. 2020) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)).

Under the APA, a claimant must also establish that their interests are "arguably within the zone of interests to be protected or regulated by the statute." *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 224 (2012) (quoting *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970)). This test is not "especially demanding" and requires only that the interest is "sufficiently congruent with those of the intended beneficiaries that the litigants are not more likely to frustrate than to further the statutory objectives." *City & Cnty. of San Francisco*, 981 F.3d at 755 (citations omitted).

Plaintiffs assert the following direct harm: (1) unrecoverable costs on the States' Medicaid and other state-funded health care programs from increased surgical abortions and pregnancy care, (2) practice restrictions on providers and pharmacists, including state employees, and (3) unrecoverable costs in implementing systems to comply with the 2023 REMS' patient agreement and

licensure requirements. ECF Nos. 3 at 29–30; 60 at 7–10 (citations to the record omitted).

Plaintiffs have shown a reasonably probable threat to their economic interests in the form of unrecoverable costs that are fairly traceable to the 2023 REMS, which are allegedly in violation of the APA. *See California v. Azar*, 911 F.3d 558, 571–73 (9th Cir. 2018) (finding state had standing due to economic interests where state was responsible for reimbursing women who will seek contraceptive care through state-run programs). Therefore, Plaintiffs have established standing.

2. Administrative Exhaustion

Defendants contend Plaintiffs failed to exhaust their administrative remedies by not filing a citizen petition under the 2023 REMS. ECF No. 51 at 14–19. Plaintiffs maintain that a new citizen petition would be futile where FDA had the same information and arguments prior to the January 2023 REMS decision. ECF No. 60 at 4–7.

Under the APA, "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. However, the APA requires a plaintiff to "exhaust available administrative remedies before bringing their grievances to federal court." *Idaho Sporting Congress, Inc. v.*

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Rittenhouse, 305 F.3d 957, 965 (9th Cir. 2002) (citing 5 U.S.C. § 704).

Administrative exhaustion allows "the administrative agency in question to exercise its expertise over the subject matter and to permit the agency an opportunity to correct any mistakes that may have occurred during the proceeding, thus avoiding unnecessary or premature judicial intervention into the administrative process." Buckingham v. Secretary of U.S. Dept. of Agr., 603 F.3d 1073, 1080 (9th Cir. 2020) (internal citation omitted). While the APA does not mandate a process by which a plaintiff must exhaust remedies, the APA provides for exhaustion "to the extent that it is required by statute or by agency rule as a prerequisite to judicial review." Darby v. Cisneros, 509 U.S. 137, 153 (1993).

As relevant here, the FDA created a regulatory mechanism by which interested persons may challenge agency activities under the Food, Drug, and Cosmetic Act ("FDCA"). See 21 C.F.R. §§ 10.1(a), 10.25(a), 10.45(b). "An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action in the form of a citizen petition." 21 C.F.R. § 10.25(a). "A request that the Commissioner take ... administrative action must first be the subject of a final administrative decision based upon a petition submitted under § 10.25(a) ... before any legal action is filed in a court complaining of the action or failure to act." 21 C.F.R. § 10.45(b). The purpose of administrative exhaustion is

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to prevent "premature interference with agency processes, so that the agency may function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review." *Tamosaitis v. URS Inc.*, 781 F.3d 468, 478 (9th Cir. 2017).

Under exceptional circumstances, administrative exhaustion of an APA claim is not required. *See Anderson v. Babbitt*, 230 F.3d 1158, 1164 (9th Cir. 2000). Exceptional circumstances include where there is "objective and undisputed evidence" of administrative bias rendering pursuit of an administrative remedy futile. *Id.* (brackets omitted); *see also SAIF Corp./Oregon Ship v. Johnson*, 908 F.2d 1434, 1441 (9th Cir. 1990). Thus, where it appears the agency's position is "already set" and it is "very likely" what the result would be, such recourse is futile. *El Rescate Legal Servs., Inc. v. Exec. Off. of Immigr. Rev.*, 959 F.2d 742, 747 (9th Cir. 1991) (citation omitted); *see also Chinook Indian Nation v. Zinke*, 326 F. Supp. 3d 1128, 1144 (W.D. Wash. 2018) ("There is virtually no chance that requiring Plaintiffs to go through [agency's] formal request process will make any difference.").

In 2020, fifteen Plaintiff States asked FDA to eliminate the REMS patient agreement and certification requirements as "onerous and medically unnecessary" and received a form response from FDA. ECF No. 60 at 5. In 2021, FDA

conducted a "full review" of REMS, including information about comparator drugs with mifepristone. ECF No. 60 at 7. In 2022, the ACOG and other medical and professional healthcare access organizations petitioned FDA to, in part, eliminate the REMS as medically unnecessary and unduly burdensome for uses of mifepristone, primarily for miscarriage management. ECF Nos. 35 at 47, ¶ 139; 60 at 4; 61-1. FDA rejected ACOG's citizen petition. ECF No. 35 at 51, ¶ 144.

Based on the information and requests already put forth before FDA, FDA cannot credibly argue that its decision on the Mifepristone REMS Program would change upon another citizen petition. *See, e.g.*, ECF Nos. 51-5 at 22–23 (assessing whether to retain Mifeprex REMS); 61-13 at 2 (chronology of FDA communications). Thus, the Court finds that administrative exhaustion through a citizen petition on the January 2023 REMS would be futile.

3. APA Claim

Plaintiffs assert they are likely to succeed on the merits of the claim that the 2023 REMS is contrary to law and arbitrary and capricious under the APA. ECF No. 3 at 19–29.

To obtain injunctive relief, Plaintiff must show that there are "serious questions going to the merits" of its claims or that it is "likely to succeed on the merits." *Cottrell*, 632 F.3d at 1131; *Farris*, 677 F.3d at 865. Under the APA, a court shall "hold unlawful and set aside agency action, findings, and conclusions

1 found to be ... arbitrary [and] capricious ... or otherwise not in accordance with 2 law [or] in excess of statutory ... authority, or limitations." 5 U.S.C. § 706(2)(A), 3 (C). Courts must uphold an agency action unless it (1) "relied on factors which 4 Congress has not intended it to consider," (2) "entirely failed to consider an 5 important aspect of the problem," (3) "offered an explanation for its decision that 6 runs counter to the evidence before the agency," or (4) the "decision is so 7 implausible that it could not be ascribed to a difference in view or the product of 8 agency expertise." Turtle Island Restoration Network v. U.S. Dep't of Commerce, 9 878 F.3d 725, 732–33 (9th Cir. 2017) (internal quotation marks omitted). Additionally, a decision is arbitrary and capricious if it is internally inconsistent 10 11 with the underlying analysis. Nat'l Parks Conservation Ass'n v. EPA, 788 F.3d 12 1134, 1141 (9th Cir. 2015). Review is "at its most deferential" regarding an 13 agency's scientific determinations within its area of expertise. Baltimore Gas & 14 Elec., Co. v. Nat. Res. Def. Council, Inc., 462 U.S. 87, 103 (1982). 15 Regulations are valid if they are "consistent with the statute under which 16 they are promulgated." *United States v. Larionoff*, 431 U.S. 864, 873 (1977). 17 Under the FDCA, a new drug cannot be marketed and prescribed until it undergoes 18 a rigorous approval process to determine that it is safe and effective. 21 U.S.C. § 19 355. For certain drugs, a risk evaluation and mitigation strategy (REMS) is

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required when the agency determines, after considering six factors, it is "necessary

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to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 1 2 355-1(a)(1). An existing REMS may be modified or removed to "ensure the benefits of the drug outweighs the risks of the drug [or] minimize the burden on the 3 4 health care delivery system of complying with the strategy." 21 U.S.C. § 355-1(g)(4)(B). 5 6 Moreover, a REMS may include elements that are necessary to assure safe 7 use [ETASU] due to a drug's "inherent toxicity or potential harmfulness" if the 8 drug has "been shown to be effective, but is associated with a serious adverse drug 9 experience, can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a specific serious risk listed in the 10 11 labeling of the drug." 21 U.S.C. § 355-1(f)(1)(A). A "serious adverse drug experience" is one that results in: 12 death; an adverse drug experience that places the patient at immediate 13 risk of death...; inpatient hospitalization or prolongation of existing hospitalization; a persistent or significant incapacity or substantial 14 disruption of the ability to conduct normal life functions; or a 15 congenital anomaly or birth defect; or based on appropriate medical judgment, may jeopardize the patient and may require a medical or surgical intervention to prevent [such] an outcome. 16 21 U.S.C. § 355-1(b)(4)(A). 17 18 If the FDA determines ETASU is required, the ETASU shall: 19

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not be unduly burdensome on patient access to the drug, considering in particular – patients with serious or life-threatening diseases or conditions; patient who have difficulty accessing health care (such as patients in rural or medically underserved areas); and patients with functional limitations; and to the extent practicable, so as to minimize the burden on the health care delivery system – conform with [ETASU] for other drugs with similar, serious risks; and be designed to be compatible with established distribution, procurement, and dispensing systems from drugs.

21 U.S.C. § 355-1(f)(2)(C)-(D).

Plaintiffs contend that mifepristone no longer requires a REMS program with ETASU. ECF Nos. 3 at 19–21, 23–24; 60 at 11. Plaintiffs assert that (1) FDA acknowledges that serious adverse events are "exceedingly rare", (2) mifepristone's associated fatality rate is .00005%, with not a single death "casually attributed to mifepristone"(3) "all the data shows the mifepristone is among the safest drugs in the world, and safer than the vast majority of drugs for which FDA has never attempted to impose a REMS", and (4) "there is no reasoned scientific basis for subjecting it to additional burdens that are not applied to other, riskier medications." *See id.* Defendants do not address whether mifepristone qualifies for ETASU, asserting it need only determine whether modifications are appropriate under 21 U.S.C. § 355-1(g)(4)(B). *See* ECF Nos. 51 at 25; 78 at 22.

The FDA may modify or remove an approved REMS, including ETASU, if it determines "1 or more goals or elements should be ... modified, or removed from the approved strategy [in part] to ensure the benefits of the drug outweigh the

risks of the drug." 21 U.S.C. § 355-1(g)(4)(B). Implicit in this assessment is whether the drug's risks require REMS and/or ETASU. 21 U.S.C. § 355-1(a)(1), (f)(1). Thus, it would be contrary to the plain language of the statute that the agency need not consider arguments that mifepristone's REMS and ETASU should be removed in whole or part based on criteria under 21 U.S.C. § 355-1(a)(1), (f)(1).

It is not the Court's role to review the scientific evidence and decide whether mifepristone's benefits outweigh its risks without REMS and/or ETASU. That is precisely FDA's role. However, based on the present record, FDA did not assess whether mifepristone qualifies for REMS and ETASU based on the criteria set forth under 21 U.S.C. § 355-1(a)(1), (f)(1). See ECF No. 51-4. Even under a deferential review, it appears FDA failed to consider an important aspect of the problem. Turtle Island, 878 F.3d at 732. Moreover, the record demonstrates potentially internally inconsistent FDA findings regarding mifepristone's safety profile. Nat'l Parks Conservation, 788 F.3d at 1141; see, e.g., ECF Nos. 51-5 at 8–9 ("Serious adverse events ... are rare" [and] mifepristone "is safe and effective through 70 days gestation."); 51-9 (approving mifepristone for Cushing's syndrome without a REMS considering risks of fetal loss).

Therefore, the Court finds there are serious issues going to the merits of Plaintiffs' APA claims. *Cottrell*, 632 F.3d at 1131. The Court emphasizes this finding is not binding at a trial on the merits. *Univ. of Texas v. Camenisch*, 451

U.S. 390, 395 (1981). Given this determination, the Court finds it unnecessary to

address the other arguments regarding the individual ETASU currently in place. *See* ECF No. 3 at 21.

B. Irreparable Harm

Plaintiffs assert they will suffer irreparable harm from the 2023 REMS in at least three ways: (1) financial costs on Plaintiffs that cannot be compensated, (2)

burdens on Plaintiffs' institutions and providers who provide abortion care, and (3) harm to the health and well-being of patients and providers "by aggravating the

ongoing crisis of reduced access to abortion care." ECF No. 3 at 29.

A plaintiff seeking injunctive relief must "demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22 (emphasis in original). "Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with [the Supreme Court's] characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Id.* "Irreparable harm is traditionally defined as harm for which there is no adequate legal remedy, such as an award of damages." *Arizona Dream Act Coalition v. Brewer*, 757 F.3d 1053, 1068 (9th Cir. 2014). A court may imply a lack of irreparable harm where there is no "speedy action" and a plaintiff sleeps on its rights. *Lydo Enters. v. City of Las Vegas*, 745 F.2d 1211, 1213 (9th Cir. 1984).

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Plaintiffs assert that the Mifepristone REMS Program imposes costs that are not compensable where the restriction of access to mifepristone causes patients to miss the window for medication abortion, leaving patients with procedural abortion or carrying a pregnancy to term, options that impose higher costs on Plaintiffs' state-run health care programs. ECF No. 3 at 29–30. Plaintiffs also contend the ongoing implementation of the 2023 REMS modifications impose costs on Plaintiffs. *Id.* at 33. Economic costs that may not be recovered through the ordinary course of litigation satisfy the irreparable harm standard. *Idaho v. Coeur d'Alene Tribe*, 794 F.3d 1039, 1046 (9th Cir. 2015); *see also California v. U.S. Health & Human Servs.*, 390 F. Supp. 3d 1061, 1065 (N.D. Cal. 2019). The Court finds that the alleged unrecoverable economic costs in this case is sufficient to demonstrate irreparable harm. The Court need not reach Plaintiffs' other bases of irreparable harm.

Defendants argue Plaintiffs fail to show irreparable harm on two grounds: (1) the 2023 REMS loosen restrictions and (2) Plaintiffs delayed in filing this action. ECF No. 51 at 30. First, even taking Defendants' argument that the "net effect" of the 2023 REMS lessens restrictions, Plaintiffs continue to assert that *no* restrictions are necessary and the 2023 REMS impose new restrictions that Plaintiffs are still working to implement. *See* ECF No. 3 at 33. Second, as to any delay, Plaintiffs contend they did not know FDA would approve the 2023 REMS

in light of the Dobbs decision² until January 2023. ECF No. 60 at 15–16; see also 2 ECF No. 78 at 9. This is a complex case with 18 Plaintiffs. The Court finds 3 Plaintiffs' less than two-month delay from the FDA approval minimal considering 4 the record and issues in this case. Lydo, 745 F.2d at 1213. Accordingly, these are 5 not bases to deny preliminary relief based on the lack of irreparable harm. 6 Plaintiffs have satisfied this element.

C. Balancing of Equities and Public Interest

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Plaintiffs assert that the equities and public interest weigh strongly in their favor where the public's health is at stake. ECF No. 3 at 36.

When the government is a party to a case in which a preliminary injunction is sought, the balance of the equities and public interest factors merge. Drakes Bay Oyster Co. v. Jewell, 747 F.3d 1073, 1092 (9th Cir. 2014). The public's interest in health care favors a preliminary injunction where the agency's action likely "results in worse health outcomes." New York v. U.S. Dep't of Homeland Sec., 969 F.3d 42, 87 (2d Cir. 2020).

Plaintiffs contend the public has an interest in access to safe and effective medicine for those who terminate their pregnancies. ECF No. 3 at 36. Defendants contend the public interest is "best served by deferring to FDA's judgments about

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

what restrictions are necessary to ensure drugs are safe." ECF No. 51 at 32. The Court agrees with this general premise, but the allegations in this case are that FDA made findings (or failed to make findings) that the Court does not defer to, i.e. those contrary to law and those that are arbitrary and capricious. Thus, this argument does not strongly favor Defendants. Based on the public health and administrative considerations at issue in this case, Plaintiffs have shown the balance of the equities sharply tip in their favor and the public interest favors a preliminary injunction.

The Court finds Plaintiffs have satisfied the "alternative" *Cottrell* test. At this point, the Court will issue a status quo preliminary injunction but not a mandatory preliminary injunction.

D. Relief

The Court turns to Plaintiffs' remedy. Defendants contend that Plaintiffs' requested relief exceeds any permissible scope where Plaintiffs seek an order enjoining "any action to remove mifepristone from the market or otherwise cause the drug to become less available." ECF No. 51 at 33–36. Plaintiffs counter that an order enjoining Defendants from the following is appropriate: "(1) enforcing the 2023 REMS, and (2) changing the status quo to make mifepristone less available in the Plaintiff States." ECF No. 60 at 19.

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1. Type of Relief

When the Court determines a preliminary injunction is warranted, "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). "The purpose of such interim equitable relief is not to conclusively determine the rights of the parties but to balance the equities as the litigation moves forward." *California v. Azar*, 911 F.3d 558, 582 (9th Cir. 2018). In crafting a remedy, courts "need not grant the total relief sought by the applicant but may mold its decree to meet the exigencies of the particular case." *Trump v. Int'l Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017) (citation omitted).

"Ordinarily when a regulation is not promulgated in compliance with the APA, the regulation is invalid." *Paulsen v. Daniels*, 413 F.3d 999, 1008 (9th Cir. 2005) (citation omitted). "The effect of invalidating an agency rule is to reinstate the rule previously in force." *Id.* (citation omitted). "The scope of an injunction is within the broad discretion of the district court." *TrafficSchool.com, Inc. v. Edriver Inc.*, 653 F.3d 820, 829 (9th Cir. 2011).

First, the relief Plaintiffs seek by enjoining FDA from enforcing REMS is inconsistent. *Compare* ECF Nos. 3 at 37 (enjoining 2023 REMS) *with* 3-1 at 3 (enjoining REMS entirely). Enjoining REMS from mifepristone entirely is well beyond the status quo. Indeed, enjoining the 2023 REMS and returning to the

status quo would eliminate the ability of pharmacies to provide the drug, thereby reducing its availability. This runs directly counter to Plaintiffs' request.

Second, the relief Plaintiffs seek by enjoining FDA from reducing mifepristone's availability does not exceed the permissible scope of relief. In preserving the status quo, it is fair and equitable for FDA to not act with respect to the Mifepristone REMS Program until a determination is made on the merits. *See Boardman v. Pac. Seafood Grp.*, 822 F.3d 1011, 1024 (9th Cir. 2016) (finding court's prohibition on taking any further action "effectively preserved the parties' last uncontested status"); *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 30 (D.D.C. 1997) (enjoining "FDA from proceeding with any approval or review proceedings"). This is consistent with the APA authorizing courts to stay agency action "to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705.

Accordingly, Defendants are preliminary enjoined from altering the status or rights of the parties under the operative Mifepristone REMS Program until a determination on the merits.

2. Scope of Relief

As a final matter, the Court notes Plaintiffs appear to seek a nationwide injunction. *See* ECF No. 3-1.

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Generally, there is no "requirement that an injunction affect only the parties in the suit." *Bresgal v. Brock*, 843 F.2d 1163, 1169 (9th Cir. 1987). While courts have the authority to issue nationwide preliminary injunctions, the Ninth Circuit cautions they are for "exceptional cases" and that have proof of "an articulated connection to a plaintiff's particular harm." *E. Bay Sanctuary Covenant v. Barr*, 934 F.3d 1026, 1029 (9th Cir. 2019). "District judges must require a showing of nationwide impact or sufficient similarity to the plaintiff states to foreclose litigation in other districts." *Azar*, 911 F.3d at 584; *see also City & Cnty. of San Francisco v. Trump*, 897 F.3d 1225, 1244 (9th Cir. 2018) (noting record must be developed on nationwide impact).

First, the Court finds a nationwide injunction inappropriate where the record does not demonstrate a nationwide impact of sufficient similarity to Plaintiffs' situation. *Azar*, 911 F.3d at 584. Abortion restrictions vary state-by-state and Plaintiffs allege harm not shared nationwide. For example, Plaintiffs allege harm from the 2023 REMS in light of the influx of patients from states who do not have similar services available. Second, the Court finds a nationwide injunction inappropriate where there is the potential for competing litigation.³ *Id.* at 583

³ See, e.g., All. For Hippocratic Med. v. FDA, No. 2:22-cv-00223-Z (N.D. Tex. Jan. 13, 2023).

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(noting courts should consider "the equities of non-parties who are deprived the right to litigate in other forums.").

Under these circumstances, the Court declines to issue a nationwide injunction and will enter the preliminary injunction as it applies to Plaintiff States.

II. Amici Briefs

The Court has broad discretion to grant or refuse a prospective amicus participation. See Hoptowit v. Ray, 682 F.2d 1237, 1260 (9th Cir. 1982), abrogated on other grounds by Sandin v. Conner, 515 U.S. 472 (1995). Amicus may be either impartial individuals or interested parties. See Funbus Sys., Inc. v. Cal. Pub. Utils. Comm'n, 801 F.2d 1120, 1125 (9th Cir. 1986). In deciding whether to grant leave to file an amicus brief, courts should consider whether the briefing "supplement[s] the efforts of counsel, and draw[s] the court's attention to law that escaped consideration." Miller-Wohl Co., Inc. v. Comm'r of Labor & Indus. Mont., 694 F.2d 203, 204 (9th Cir. 1982). "An amicus brief should normally be allowed when ... the amicus has an interest in some other case that may be affected by the decision in the present case, or when the amicus has unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide. . . . Otherwise, leave to file an amicus curiae brief should be denied." Cmty. Ass'n for Restoration of Env't (CARE) v. DeRuyter

Bros. Dairy, 54 F. Supp. 2d 974, 975 (E.D. Wash. 1999) (internal citations omitted).

While these motions are unopposed, the proposed briefs offer no additional legal or substantive information that is particularly helpful to the Court's findings on the present motion. The briefs may be more useful during a trial on the merits. Therefore, the motions are denied.

ACCORDINGLY, IT IS HEREBY ORDERED:

- Plaintiffs' Motion for Preliminary Injunction (ECF No. 3) is GRANTED in part.
- 2. Pursuant to Federal Rule of Civil Procedure 65(a), Defendants and their officers, agents, servants, employees, attorneys, and any person in active concert or participation, are PRELIMINARILY ENJOINED from: "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 Risk Evaluation and Mitigation Strategy under 21 U.S.C. § 355-1 in Plaintiff States."
- 3. No bond shall be required. Fed. R. Civ. P. 65(c).
- Third Parties' Unopposed Motion for Leave to File Amicus Curiae Brief (ECF No. 52) is **DENIED.**

Third Parties' Unopposed Motion for Leave to File Amicus Brief (ECF
 No. 69) is **DENIED**.

The District Court Executive is directed to enter this Order and furnish

copies to counsel.

DATED April 7, 2023.



THOMAS O. RICE United States District Judge

CHAPTER 375

AN ACT concerning freedom of reproductive choice and supplementing Title 10 of the Revised Statutes, P.L.1997, c.192 (C.26:2S-1 et seq.), and Title 52 of the Revised Statutes.

BE IT ENACTED by the Senate and General Assembly of the State of New Jersey:

C.10:7-1 Findings and declarations.

- 1. The Legislature finds and declares that:
- a. In cases such as Right to Choose v. Byrne, 91 N.J. 287 (1982) and Planned Parenthood of Cent. N.J. v. Farmer, 165 N.J. 609 (2000), the New Jersey Supreme Court has recognized that the right to reproductive choice is a fundamental right enshrined in the State Constitution, that this right is independent of the United States Constitution, and that Article I, paragraph 1 of the New Jersey Constitution is independent of, and protects reproductive autonomy to an extent that exceeds the protections established under, the United States Constitution.
- b. The New Jersey Supreme Court has found that the right to reproductive choice includes the right to determine whether and when to bear children. In particular, the citizens of New Jersey may: access contraception, including emergency contraception; may not be denied public benefits based on the choice to have additional children; may choose to terminate a pregnancy; and may choose to carry a pregnancy to term.
- c. Self-determination in reproductive choice is key to helping establish equality among the genders and to allowing all people of childbearing age to participate equally in the economic and social life of the United States and the State of New Jersey.
- d. An unplanned pregnancy can disrupt educational and career plans, forcing the pregnant person to drop out of school, abandon pursuit of a college or advanced degree, accept lower-paying employment or employment with limited opportunities for advancement, or delay entrance into the workforce, which can have the effect of limiting the person's lifetime earnings and can prevent the person from following a chosen career path.
- e. The right to choose whether and when to have children allows people to more effectively plan in a way that is compatible with the person's overall life goals. Although each person retains the right to exercise the freedom of reproductive choice regardless of the health and strength of the person's interpersonal relationships, where and how the person lives, or the person's income level and overall resources, the essence of the right to reproductive choice is that people have the ability to make reproductive choices in a manner commensurate with their own personal beliefs, life plan, and moral code.
- f. Governmental restrictions on reproductive choice, by their very nature, impinge on the constitutional right to reproductive autonomy, particularly when they fail to confer any benefits to patients in the form of improved health or safety. Moreover, restrictions of this nature often have a disparate impact that is predominantly felt by persons who already experience barriers to health care access, including young people, people of color, people with disabilities, people with low income, people living in rural areas, immigrants, and people who are transgender or non-binary.
- g. The Legislature is committed to ensuring that no barriers to reproductive freedom exist in the State. Individuals have the right to make their own decisions concerning reproduction, including the right to contraception, the right to terminate a pregnancy, and the right to carry a pregnancy to term, without government interference or fear of prosecution.
- h. It is both reasonable and necessary for the State to enable, facilitate, support, and safeguard the provision of high-quality, comprehensive reproductive and sexual health care, including the full range of evidence-based information, counseling, and health care services,

to all individuals in the State, and to enable, facilitate, support, and safeguard the ability of such individuals to access affordable and timely reproductive health care services and to engage in autonomous reproductive decision-making, in consultation with health care professionals of their choosing, without fear of prosecution, discrimination, or unnecessary barriers to care. To achieve those ends, it shall be the policy of this State to:

- (1) explicitly guarantee, to every individual, the fundamental right to reproductive autonomy, which includes the right to contraception, the right to terminate a pregnancy, and the right to carry a pregnancy to term;
- (2) enable all qualified health care professionals to provide pregnancy termination services in the State;
- (3) advance comprehensive insurance coverage for reproductive care, including primary reproductive health care services, services to terminate a pregnancy, long-acting contraceptives, and long-term supplies of hormonal contraceptives, that enables the citizens of New Jersey to fully exercise their freedom of reproductive choice while recognizing the rights of certain religious employers to request an exemption from such coverage; and
- (4) ensure that all laws, rules, regulations, ordinances, resolutions, policies, standards, or parts thereof, that are currently in force or enacted in the future, conform to the provisions and the express or implied purposes of this act, and that any law, rule, regulation, ordinance, resolution, policy, standard, or part thereof that conflicts with the provisions of this act or its express or implied purposes is subject to invalidation.

C.10:7-2 Reproductive choice rights.

- 2. a. Every individual present in the State, including, but not limited to, an individual who is under State control or supervision, shall have the fundamental right to: choose or refuse contraception or sterilization; and choose whether to carry a pregnancy, to give birth, or to terminate a pregnancy. The New Jersey Constitution recognizes the fundamental nature of the right to reproductive choice, including the right to access contraception, to terminate a pregnancy, and to carry a pregnancy to term, shall not be abridged by any law, rule, regulation, ordinance, or order issued by any State, county, or local governmental authority. Any law, rule, regulation, ordinance, or order, in effect on or adopted after the effective date of this act, that is determined to have the effect of limiting the constitutional right to freedom of reproductive choice and that does not conform with the provisions and the express or implied purposes of this act, shall be deemed invalid and shall have no force or effect.
- b. The provisions of this section shall be enforceable under the "New Jersey Civil Rights Act," P.L.2004, c.143 (C.10:6-1 et seq.) or in any other manner provided by law.

C.26:2S-39 Health benefit plans, coverage for abortion, certain religious employers exempt.

3. a. Upon concluding a study and issuing a report to the Governor and the Legislature demonstrating that such a regulation is necessary, the Department of Banking and Insurance may, through regulation adopted pursuant to the "Administrative Procedure Act", P.L.1968 c.410 (C.52:14B-1 et seq.), provide that health benefit plans delivered, issued, executed, or renewed in this State, provide coverage for abortion. If the department provides for coverage pursuant to this section, then the department shall also require carriers to grant, upon request of a religious employer, an exclusion under the contract for the coverage required if the required coverage conflicts with the religious employer's bona fide religious beliefs and practices. A religious employer that obtains such an exclusion shall provide written notice thereof to covered persons and prospective covered persons, and the carrier shall provide notice to the Commissioner of Banking and Insurance in such form and manner as may be determined

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by the commissioner. The provisions of this paragraph shall not be construed as authorizing a carrier to exclude coverage for care that is necessary to preserve the life or health of a subscriber. An exclusion from an insurance coverage mandate granted to a religious employer pursuant to this section shall not be considered a violation of section 2 of P.L.2021, c.375 (C.10:7-2).

b. For the purposes of this section, "religious employer" means an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986 (26 U.S.C. s.6033), as amended.

C.52:14-17.29hh SHBC, coverage for abortion, certain religious employers exemption.

4. A contract providing hospital or medical expense benefits purchased by the State Health Benefits Commission may provide coverage for abortion. A contract providing hospital or medical expense benefits purchased by the commission shall not exclude a provider from its network or otherwise restrict services from the provider solely on the basis that the provider is a religious employer, as defined in section 3 of P.L.2021, c.375 (C.26:2S-39), that refuses to provide abortion services.

C.52:14-17.46.6q School Employees' Health Benefits Commission, coverage for abortion, certain religious employers exemption.

- 5. A contract providing hospital or medical expense benefits purchased by the School Employees' Health Benefits Commission may provide coverage for abortion. A contract providing hospital or medical expense benefits purchased by the commission shall not exclude a provider from its network or otherwise restrict services from the provider solely on the basis that the provider is a religious employer, as defined in section 3 of P.L.2021, c.375 (C.26:2S-39), that refuses to provide abortion services.
 - 6. This act shall take effect immediately.

Approved January 13, 2022.

CHAPTER 51 (CORRECTED COPY)

AN ACT concerning reproductive health care services, supplementing Title 2A of the New Jersey Statutes, and amending P.L.1978, c.73.

BE IT ENACTED by the Senate and General Assembly of the State of New Jersey:

C.2A:84A-22.18 Definitions.

1. As used in sections 1 and 2 of P.L.2022, c.51 (C.2A:84A-22.18 and C.2A:84A-22.19): "Person" includes an individual, partnership, association, limited liability company, or corporation.

"Reproductive health care services" means all medical, surgical, counseling, or referral services relating to the human reproductive system including, but not limited to, services relating to pregnancy, contraception, or termination of a pregnancy.

- a. Except as provided in sections 3 through 7 of P.L.1968, c.185 (C.2A:84A-22.3 through 2A:84A-22.7), section 1 of P.L.1970, c. 313 (C.2A:84A-22.8), section 29 of P.L.1968, c.401 (C.45:8B-29), and subsection b. of this section, in any civil action or proceeding preliminary thereto or in any probate, legislative or administrative proceeding, a covered entity, as set forth in the medical privacy and security rules pursuant to Parts 160 and 164 of Subchapter C of Subtitle A of Title 45 of the Code of Federal Regulations, established pursuant to the "Health Insurance Portability and Accountability Act of 1996," Pub.L.104-191, shall not disclose, unless the patient or that patient's conservator, guardian, or other authorized legal representative explicitly consents in writing to the disclosure:
- (1) any communication made to the covered entity, or any information obtained by the covered entity from, a patient or the conservator, guardian, or other authorized legal representative of a patient relating to reproductive health care services that are permitted under the laws of this State; or
- (2) any information obtained by personal examination of a patient relating to reproductive health care services that are permitted under the laws of this State.

A covered entity shall inform the patient or the patient's conservator, guardian, or other authorized legal representative of the patient's right to withhold such written consent at or before the time reproductive health care services are rendered or at such time as the patient discloses any information relating to reproductive health care services that have been previously rendered.

- b. Written consent of the patient or the patient's conservator, guardian, or other authorized legal representative shall not be required for the disclosure of any communication or information:
 - (1) pursuant to the laws of this State or the Rules of Court;
- (2) by a covered entity against whom a claim has been made, or there is a reasonable belief will be made, in an action or proceeding, to the covered entity's attorney or professional liability insurer or insurer's agent for use in the defense of the action or proceeding;
- (3) to the Commissioner of Health, Human Services, or Banking and Insurance, or any professional licensing board operating under the authority of the Division of Consumer Affairs in the Department of Law and Public Safety for records of a patient of a covered entity in connection with an investigation of a complaint, if the records are related to the complaint; or
- (4) if child abuse, abuse of an elderly individual, abuse of an individual who is incapacitated, or abuse of an individual with a physical or mental disability is known or in good faith suspected. For the purposes of this paragraph, the provision of or material support for reproductive health care services that are permitted under the laws of this State shall not constitute abuse.

Nothing in this subsection shall be construed to conflict with or displace any requirements or conditions for disclosure set forth under 45 C.F.R. ss.160.203 and 164.514.

c. Nothing in this section shall be construed to impede the lawful sharing of medical records as permitted by State or federal law or the Rules of Court.

2A:84A-22.19 Disclosure of information, certain, expending of resources, certain, prohibited.

- 2. A public entity of this State or employee, appointee, officer or official or any other person acting on behalf of a public entity shall not provide any information or expend or use time, money, facilities, property, equipment, personnel or other resources in furtherance of any interstate investigation or proceeding seeking to impose civil or criminal liability upon a person or entity for:
- (1) the provision, receipt, or seeking of, or inquiring or responding to an inquiry about, reproductive health care services, as defined in section 1 of P.L.2022, c.51 (C.2A:84A-22.18), that are legal in this State; or
- (2) assisting, advising, aiding, abetting, facilitating, soliciting, or conspiring with any person or entity providing, receiving, seeking, or inquiring or responding to an inquiry about, reproductive health care services, as defined in section 1 of P.L.2022, c.51 (C.2A:84A-22.18), that are legal in this State.

This section shall not apply to any investigation or proceeding when the conduct subject to potential liability under the investigation or proceeding would be subject to liability under the laws of this State if committed in this State. This section shall not apply if it is necessary for the agency or person to engage in conduct otherwise prohibited by this section in order to comply with a valid order issued by a court with jurisdiction over the agency or person, or to comply with applicable provisions of State or federal law.

3. Section 8 of P.L.1978, c.73 (C.45:1-21) is amended to read as follows:

C.45:1-21 Refusal to license or renew, grounds.

- 8. A board may refuse to admit a person to an examination or may refuse to issue or may suspend or revoke any certificate, registration or license issued by the board upon proof that the applicant or holder of such certificate, registration or license:
- a. Has obtained a certificate, registration, license or authorization to sit for an examination, as the case may be, through fraud, deception, or misrepresentation;
- b. Has engaged in the use or employment of dishonesty, fraud, deception, misrepresentation, false promise or false pretense;
- c. Has engaged in gross negligence, gross malpractice or gross incompetence which damaged or endangered the life, health, welfare, safety or property of any person;
 - d. Has engaged in repeated acts of negligence, malpractice or incompetence;
- e. Has engaged in professional or occupational misconduct as may be determined by the board;
- f. Has been convicted of, or engaged in acts constituting, any crime or offense that has a direct or substantial relationship to the activity regulated by the board or is of a nature such that certification, registration or licensure of the person would be inconsistent with the public's health, safety, or welfare, provided that the board shall make this determination in a manner consistent with section 2 of P.L.2021, c.81 (C.45:1-21.5). For the purposes of this subsection a judgment of conviction or a plea of guilty, non vult, nolo contendere or any other such disposition of alleged criminal activity shall be deemed a conviction;

- g. Has had his authority to engage in the activity regulated by the board revoked or suspended by any other state, agency or authority for reasons consistent with this section;
- h. Has violated or failed to comply with the provisions of any act or regulation administered by the board;
- i. Is incapable, for medical or any other good cause, of discharging the functions of a licensee in a manner consistent with the public's health, safety and welfare;
- j. Has repeatedly failed to submit completed applications, or parts of, or documentation submitted in conjunction with, such applications, required to be filed with the Department of Environmental Protection;
- k. Has violated any provision of P.L.1983, c.320 (C.17:33A-1 et seq.) or any insurance fraud prevention law or act of another jurisdiction or has been adjudicated, in civil or administrative proceedings, of a violation of P.L.1983, c.320 (C.17:33A-1 et seq.) or has been subject to a final order, entered in civil or administrative proceedings, that imposed civil penalties under that act against the applicant or holder;
- 1. Is presently engaged in drug or alcohol use that is likely to impair the ability to practice the profession or occupation with reasonable skill and safety. For purposes of this subsection, the term "presently" means at this time or any time within the previous 365 days;
- m. Has prescribed or dispensed controlled dangerous substances indiscriminately or without good cause, or where the applicant or holder knew or should have known that the substances were to be used for unauthorized consumption or distribution;
- n. Has permitted an unlicensed person or entity to perform an act for which a license or certificate of registration or certification is required by the board, or aided and abetted an unlicensed person or entity in performing such an act;
 - o. Advertised fraudulently in any manner.

The division is authorized, for purposes of facilitating determinations concerning licensure eligibility, to require the fingerprinting of each applicant in accordance with applicable State and federal laws, rules and regulations. Each applicant shall submit the applicant's name, address, and written consent to the director for a criminal history record background check to be performed. The division is authorized to receive criminal history record information from the State Bureau of Identification in the Division of State Police and the Federal Bureau of Investigation. Upon receipt of such notification, the division shall forward the information to the appropriate board which shall make a determination regarding the issuance of licensure. The applicant shall bear the cost for the criminal history record background check, including all costs of administering and processing the check, unless otherwise provided for by an individual enabling act. The Division of State Police shall promptly notify the division in the event an applicant or licensee, who was the subject of a criminal history record background check pursuant to this section, is convicted of a crime or offense in this State after the date the background check was performed.

Notwithstanding the provisions of any law, rule, or regulation to the contrary, a board shall not refuse to admit a person to an examination and shall not suspend, revoke, or refuse to renew any certificate, registration, or license issued by the board based solely on the applicant's or the certificate, registration, or license holder's provision of, authorization of, participation in, referral for, or assistance with any health care, medical service, or procedure related to an abortion for a person who resides in a jurisdiction where the provision, authorization, participation, referral, or assistance is illegal, if the provision, authorization, participation, referral, or assistance would not be a basis for refusing to admit a person to an examination or for suspending, revoking, or refusing to renew a certificate, registration, or license in this State.

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For purposes of this act:

"Completed application" means the submission of all of the information designated on the checklist, adopted pursuant to section 1 of P.L.1991, c.421 (C.13:1D-101), for the class or category of permit for which application is made.

"Permit" has the same meaning as defined in section 1 of P.L.1991, c.421 (C.13:1D-101).

4. This act shall take effect immediately.

Approved July 1, 2022.

CHAPTER 50

AN ACT barring extradition of persons under certain circumstances related to actions concerning reproductive health care services and supplementing chapter 160 of Title 2A of the New Jersey Statutes.

BE IT ENACTED by the Senate and General Assembly of the State of New Jersey:

C.2A:160-14.1 Surrender of individuals seeking reproductive health care services lawful in New Jersey, prohibited.

- 1. Notwithstanding the provisions of N.J.S.2A:160-14, the Governor shall not surrender, on demand of the executive authority of any other state, any person who:
 - a. is found in this State;
- b. was not in the state whose executive authority is making the demand at the time of the commission of the alleged crime and has not fled therefrom; and
- c. is charged in the state whose executive authority is making the demand with providing, receiving, assisting in providing or receiving, providing material support for, or traveling to obtain reproductive health care services that are permitted under the laws of this State, including on any theory of vicarious, joint, several or conspiracy liability.

As used in this section, "reproductive health care services" means all medical, surgical, counseling, or referral services relating to the human reproductive system including, but not limited to, services relating to pregnancy, contraception, or termination of a pregnancy.

2. This act shall take effect immediately.

Approved July 1, 2022.

New Jersey Office of the Attorney General

Know Your Rights



Abortion Rights in New Jersey

1. Is abortion still legal in New Jersey, even after the Supreme Court overturned Roe v. Wade?

Yes. Abortion is still legal in New Jersey. In January 2022, the legislature passed and Governor Phil Murphy signed a <u>law</u> guaranteeing you the right to terminate or keep a pregnancy.

2. How does the Supreme Court's decision overturning Roe v. Wade impact the right to abortion in New Jersey?

It doesn't. While devastating for people in the many states where abortion will be banned or severely restricted, the Supreme Court's decision did not ban or limit the right to abortion in New Jersey. You still have the right to an abortion in New Jersey.

3. Can I get a prescription for medication abortion in New Jersey?

Yes. Patients in New Jersey have options for both medication and procedure-based abortion care. Talk to your provider about the care best for you.

4. Can telehealth be used to get a prescription for medication abortion in New Jersey?

Yes. You can get a prescription for medication abortion through an online telehealth appointment with a New Jersey provider, and pills may be mailed to you. Medication abortion may not be right for everyone, so talk to your provider about the care best for you.

5. Can I get abortion care in New Jersey if I live in another state?

Yes. You do not have to be a resident of New Jersey to receive care here.

6. Are there limits on when I can get an abortion in New Jersey?

Speak with your provider. New Jersey protects the ability of individuals to make decisions in collaboration with their provider throughout pregnancy.

7. I'm under 18 years old. Can I get an abortion in New Jersey without my parents' permission?

Yes. New Jersey protects the right to abortion for all pregnant persons, including minors.

8. What do I do if I need an abortion but can't afford one?

New Jersey Family Care (Medicaid), as well as many private health plans, cover abortion. So check with your insurer. Even without insurance, financial assistance for affordable and confidential abortion care is often available. Speak with your provider.

- 9. How can I find an abortion provider in New Jersey?
 - **Abortion Finder:** With more than 750 health centers, AbortionFinder.org features the most comprehensive directory of trusted (and verified) abortion service providers in the United States.
 - Planned Parenthood: Find abortion clinics near you.
 - National Abortion Federation: Call their Hotline at 800-772-9100.
- 10. Who do I call if I think my right to abortion has been violated in New Jersey?

If you are subject to harassment or intimidation while attempting to obtain abortion care, contact local law enforcement or your **County Prosecutor**.

June 29, 2022













NJOAG.gov

FAQs for Those Who Assist People Seeking Abortions in New Jersey

This document is for informational purposes only, is not intended as legal advice, and does not substitute for consulting with a lawyer about your particular facts and circumstances. This document does not constitute a solicitation, and your use of this document does not create any attorney-client relationship between you and Lowenstein Sandler. We do not represent that the content of this document is correct, complete, or up-to-date, or that it reflects current legal developments.

INDIVIDUAL RISK ASSESSMENTS

Many of the responses below are intended to identify circumstances in which you should consider seeking legal advice relating to assistance you may be providing to out-of-state patients obtaining legal abortions in New Jersey. In the aftermath of the United States Supreme Court decision in *Dobbs v. Jackson Women's Health Organization*, a significant number of states have enacted, or will soon enact, laws that severely restrict or ban abortion, which will lead people in those states to travel to states like New Jersey where they can get a legal abortion. Those who help such out-of-state patients obtain care in New Jersey can become targets of opponents of legal abortion in other states. This means that there is some risk involved. The risk may be low, and you are lucky to be in New Jersey, where the state has taken meaningful steps to protect you, as you'll see below. But the risk still exists. Part of the reason to contact a lawyer is for advice on how to mitigate the risk. The extent of the risk will depend on a number of factors, and these FAQs do not attempt to assess the risk based on your individual circumstances. Our goal is not to deter you, but to inform you and help you identify when an individual risk assessment is especially important.

SAFE INTERNET SEARCHES AND PHONE CALLS

1. If I'm researching abortion online, are there ways to keep my searches private?

Before you read these FAQs, you might want to educate yourself on how to keep your data more private.

Good resources for understanding steps you can take to minimize your digital footprint and improve your privacy and security are available at the <u>Digital Defense Fund Guide to Abortion Privacy</u> and the <u>Electronic Frontier Foundation Security and Privacy Tips for People Seeking an Abortion</u>. The <u>Repro Legal Helpline</u> also provides <u>information on digital safety</u>.

The safest course is not to communicate online, by messaging app, or by text about anything you want to keep private.

2. Are there ways to keep my phone calls private?

Phone calls can be made more secure by using "burner" phones, calling from phones that are not tied to your identity, using *67 to block your caller ID, or using services like Google Voice or other apps that permit anonymous phone calls.

BASIC RIGHTS TO ABORTION IN NEW JERSEY

3. Is abortion still legal in New Jersey?

Yes, abortion is still legal in New Jersey. Abortion is an independent and fundamental right protected by both the New Jersey Constitution and state legislation. The United States Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* does **not** diminish the right to abortion in New Jersey.

4. Does New Jersey have abortion restrictions (waiting period, gestational limit, parental involvement, etc.)?

New Jersey places very few legal restrictions on abortion. There are no waiting period or parental involvement laws. Providers offer care based on each patient's specific circumstances, and if they are unable to provide care, they will usually refer the patient for other assistance.

OTHER STATE LAWS

5. How can I find out about the law in the state where the person I am helping lives?

If you want to learn what the law is in a particular state, you can check these resources:

- Center for Reproductive Rights' State Law Tracker
- Guttmacher Institute Interactive Map
- New York Times' Tracker
- Washington Post's Tracker

State laws are changing rapidly. If you want to know more about the legal risks in a particular state, you can also contact the Repro Legal Helpline.

LIABILITY IN GENERAL

6. What threats are arising against those who help someone from a state that bans or restricts abortion (a "ban state") obtain an abortion by providing them with financial assistance, housing, transportation, or other resources (i.e., being a "helper")? Can I be prosecuted or sued under the laws of a ban state?

You're okay under the laws of New Jersey.

Abortions are legal in New Jersey, and you cannot be prosecuted or sued under the laws of New Jersey for helping someone from a ban state obtain a legal abortion in New Jersey. However, New Jersey law cannot protect you from being sued or prosecuted under the laws of another state.

You face potential risks under the criminal abortion laws of ban states.

You may face legal risks if you help someone from a state where abortion is illegal travel to New Jersey to obtain abortion care.

It is normally safe for a person to travel to a state and engage in conduct that is legal in the state the person is visiting. For example, people can travel to Las Vegas to gamble even if gambling is illegal in their home state, and their home state should not be able to punish them or anyone who facilitated their gambling.

There is a risk, however, that the normal rules will not stop prosecutors in other states from trying to apply their existing criminal laws to prevent people from helping residents of ban states get legal abortions in other states. We do not yet know how courts in ban states will react to such law enforcement tactics.

As of the date of these FAQs, no state has passed a law that explicitly makes it a crime to help an abortion patient from a ban state obtain an abortion in a state where it is legal (an "access state").

You face potential risks from private people who might sue you.

Some states have already passed laws that enable private citizens to sue people who help others obtain abortions, and other states may follow. Such laws should not apply to conduct that occurs entirely outside the ban state, but we cannot be certain how courts will interpret them.

You might want to talk to a lawyer.

You can call the number below to get advice from a lawyer about the risk of assisting individuals from ban states obtain an abortion in New Jersey. You can also try the <u>Repro Legal Helpline</u>.

If the out-of-state abortion patient you are helping is a minor, additional considerations arise. See Q.7.

New Jersey has passed some laws intended to protect people who facilitate access to abortion care in New Jersey from out-of-state consequences, but these laws cannot eliminate all risk. See Qs.10, 12.

7. Is there additional legal risk associated with helping a minor from a ban state travel to New Jersey for an abortion?

Yes. Under New Jersey law, minors have access to legal and confidential abortion so long as they are able to provide informed consent, meaning they can understand the risks and benefits of the abortion and its alternatives. New Jersey law does not require minors to notify or seek consent from a parent or guardian.

Assistance may include contributing to the cost of the abortion or related expenses, transporting the minor, providing housing during the trip, or otherwise helping the minor travel out of state for an abortion.

Because minors may, as a legal matter, need their parent's or guardian's permission to travel, a person (even possibly a parent or guardian) could face serious risks for helping a minor travel for an abortion in another state. *It is critical to consult with a lawyer*, especially if you are helping a minor who is traveling from a ban state to New Jersey for an abortion without parental knowledge or permission.

You can call the number below or try the <u>Repro Legal Helpline</u> to get advice from a lawyer about the risk of assisting individuals from ban states obtain an abortion in New Jersey.

8. Can I be criminally liable or sued under the laws of another state if I donate to an abortion fund or other organization that is helping people travel to access states?

Maybe. New Jersey law does not prohibit donations to an abortion fund or to organizations assisting individuals with traveling to access states for an abortion. As of the date of these FAQs, we are not aware of any law that makes it a crime to provide financial or other support to someone seeking a lawful abortion in an access state. There is also significant constitutional protection for expressing your support through donations to abortion funds and other organizations that offer assistance.

Prosecutors in ban states might nevertheless try charging donors, depending on the laws of the particular state where the donor sends the money and how the money is used. Similarly, private citizens might sue donors for helping fund or support abortions for patients from ban states.

While the full extent of the risks is unknown, making donations to and working with established and trusted organizations that are assisting people in finding legal reproductive health care services probably poses less risk than contributing to a public GoFundMe page. For a non-exhaustive list of trusted organizations, see Q.16.

9. Can I get in trouble if I post on social media about helping people in ban states get abortions?

Yes. As explained above, prosecutors or others in ban states could try to take action against those who help someone from a ban state obtain an abortion. See Q.6. Any information you provide on social media or in any other public forum is not subject to any privacy protections and may be used against you or others in criminal or civil investigations or proceedings.

10. Will out-of-state prosecutors or individuals who sue me be able to get my phone records, emails, bank statements, or other information about me?

Maybe. A recently enacted <u>state law</u> prohibits New Jersey courts and law enforcement officers from cooperating with investigations by out-of-state actors into reproductive health services that are legal in New Jersey. New Jersey courts have not yet assessed this new law, and courts and prosecutors may not always be able to tell when an out-of-state investigation relates to a legal abortion or other reproductive health care. Still, the law prohibits public employees and entities from assisting in cross-state investigations of reproductive health services (including abortions) that are legal in New Jersey. While this law provides protection, it cannot guarantee the confidentiality of information.

Out-of-state prosecutors and private litigants often use subpoenas or court orders to get information that is not publicly available on social media or elsewhere. Such demands may seek emails, bank information, and phone records regarding any assistance (financial or otherwise) provided to an out-of-state individual who obtained an abortion in New Jersey. The subpoenas may go, for example, to individuals, health providers or insurers, financial institutions, a search engine, an app, or email/phone service providers that store such records in New Jersey.

If the recipient of the subpoena is a health provider, health insurer/plan, or processor of health information for a provider or insurer/plan, <u>another new law</u> increases confidentiality protections. This law requires health care providers, insurers, and processors to get the patient's written consent before disclosing information about reproductive health services in any civil, administrative, or legislative proceeding. Other individuals or entities who receive a subpoena are permitted to disclose such information, but those located in New Jersey cannot be forced to do so.

Only a New Jersey court can force a person or entity in New Jersey to respond to a subpoena. Because the <u>law</u> now prohibits New Jersey courts from assisting in any out-of-state investigation into an abortion that is legal in New Jersey, the subpoena probably cannot be enforced in New Jersey.

If your financial or location information is stored outside New Jersey, such as in credit card records or E-ZPass records associated with driving out of state, those records may be subject to disclosure in other states based on those states' laws.

CRIMINAL LIABILITY

11. What happens if a ban state issues a warrant for my arrest? What happens if a ban state files criminal charges against me? Can I travel to that state?

If a ban state issues a warrant for your arrest or files criminal charges against you, and you are physically in that state, there is a significant risk that you will be arrested and detained. Even

a short trip (e.g., a layover at an airport) can give the ban state an opportunity to enforce its criminal laws against you.

If you are planning to travel to a ban state that is investigating you or has initiated criminal proceedings against you, it is very important that you consult with a lawyer before entering the state. You can call the number below. The Repro Legal Helpline may also be able to connect you with a lawyer who has knowledge of the criminal law in the state you plan to visit.

12. Am I safe from extradition from NJ to the state that issued an arrest warrant or filed criminal charges against me?

It depends. New Jersey law protects individuals who face out-of-state consequences for engaging in activity that is lawful in New Jersey, but New Jersey law cannot eliminate all risk.

The police in a ban state cannot cross state lines to arrest you in a different state. Instead, the ban state must use a process called extradition to have you taken into custody in a different state and then transferred to their state to face the charges against you.

New Jersey recently enacted a <u>law</u> that protects people from extradition in some circumstances. Under the law, New Jersey will not extradite you to a state that has charged you with a crime that involves helping someone obtain reproductive health services that are legal in New Jersey. New Jersey also will not extradite you for helping someone obtain a legal abortion in another state, if that abortion would also have been legal in New Jersey. But the law has not yet been tested in court.

The law also has an exception. New Jersey will extradite a person who was in the state making the extradition demand at the time of the alleged crime and fled that state. This means that if a ban state charges you with a crime based on your alleged conduct in that state, and that state asks New Jersey to send you back there for criminal prosecution, New Jersey law will not prevent your extradition. If there is a demand for your extradition, you should immediately consult a lawyer.

To the extent that you are transporting **minors** from their home states to New Jersey for abortions or providing other related support to minors, you should consult with counsel regarding the risk of extradition. See Q.7.

You can contact the <u>Repro Legal Defense Fund</u> if you have been charged with an abortion-related crime. If you are a New Jersey resident, you can also call the number below.

13. What happens if a ban state issues a warrant for my arrest and I travel to a different state? Could I be extradited to the ban state?

Maybe. The New Jersey extradition statute can only protect you from being extradited from New Jersey. If you travel to another state—even a state that protects the right to abortion—and the ban state that issued a warrant against you learns of your presence in the other state and demands extradition, you could be detained and extradited. Whether the state you are visiting

will extradite you will depend on the laws of that state. If an active warrant or criminal charges are pending against you in another state, you should consult with legal counsel to assess your risk before traveling out of state. The <u>Repro Legal Helpline</u> may be able to connect you with a lawyer who has knowledge of the criminal law in the state(s) you plan to visit.

CIVIL LIABILITY

14. If private citizens sue me, can they sue me in their state? Can they sue me in NJ?

A private citizen (a "plaintiff") who brings a lawsuit against someone (a "defendant") who lives in another state may have a choice of where to file. Federal or state law will determine where the plaintiff is allowed to file. If the plaintiff files the case in a ban state, you might have an opportunity to ask the court to move the proceedings to your state.

No matter where the case is filed, the court will decide whether there has been a violation of the law the plaintiff claims the defendant violated. This will normally be the law of a ban state. New Jersey law provides no basis for suing someone for assisting a patient in obtaining a legal abortion in the state.

While there is no law that prevents a party from filing a lawsuit against you, there are court rules in most states that allow you to pursue attorney's fees and sanctions against parties who file frivolous lawsuits against you.

15. Do I have to appear and answer such a suit? What happens if I travel to the state where the lawsuit was filed?

If you are sued for helping patients from ban states get legal abortions in New Jersey, you should consult with counsel. You should not ignore a lawsuit filed against you. There may be grounds for dismissal of the lawsuit, and a lawyer can advise you of your best course of action.

If you travel to a ban state where a civil lawsuit was filed against you, there is a risk that the plaintiff could serve you with process in that state and the court would then have the authority to proceed with the lawsuit against you in that state. Therefore, it may be advisable to avoid travel to ban states under those circumstances. Again, you should consult with counsel if a lawsuit has been filed against you.

HOW TO HELP

16. How can I support people seeking abortions in New Jersey?

If you want to help people living in ban states obtain reproductive health services in New Jersey or other access states, we encourage you to work with established and trusted organizations.

Below are non-exhaustive lists of resources that might be helpful.

You can donate to the following abortion funds that help pay for the costs associated with getting an abortion:

New Jersey Abortion Access Fund (NJAAF)

National Abortion Federation (NAF)

<u>National Network of Abortion Funds</u> (NNAF), or the <u>National Network of Abortion</u> <u>Funds-affiliated fund in your state</u>

Women's Reproductive Rights Assistance Project (WRRAP)

Indigenous Women Rising

You can donate directly to abortion providers in New Jersey to help them meet the increased demand for their services and assist patients with access.

New Jersey has many Planned Parenthood locations

Cherry Hill Women's Center accepts donations:

https://www.thewomenscenters.com/donate/ or

https://www.gofundme.com/f/dmac44-twc-abortion-access-fund

Keep Our Clinics channels funds to independent providers (note that this is a nationwide organization)

You can donate to funds that help people with the logistics of obtaining an abortion:

Apiary Collective

Brigid Alliance

You can volunteer with an abortion fund or clinic to support their work and can serve as a clinic escort. (Clinic escorts help patients get to the clinic door with as little interference and harassment from protesters and picketers as possible.)

Volunteer as a clinic escort with Cherry Hill Women's Center: http://thewomenscenters.com/volunteer/

If you are a lawyer looking to help, you can check in with these organizations:

Lawyers for Good Government

If/When/How RJ Lawyers Network

FAQS for People Seeking Abortions in New Jersey

This document is for informational purposes only, is not intended as legal advice, and does not substitute for consulting with a lawyer about your particular facts and circumstances. This document does not constitute a solicitation, and your use of this document does not create any attorney-client relationship between you and Lowenstein Sandler. We do not represent that the content of this document is correct, complete, or up-to-date, or that it reflects current legal developments.

SAFE INTERNET SEARCHES AND PHONE CALLS

1. If I'm researching abortion online, are there ways to keep my searches private?

Before you read these FAQs, you might want to educate yourself on how to keep your data more private.

Good resources for understanding steps you can take to protect your online privacy and security are available at the <u>Digital Defense Fund Guide to Abortion Privacy</u> and the <u>Electronic Frontier Foundation Security and Privacy Tips for People Seeking an Abortion</u>. The <u>Repro Legal Helpline</u> also provides <u>information on digital safety</u> for abortion-seekers.

In addition, specific apps, such as menstrual cycle trackers, may store information that relates to your reproductive health care. You may want to consider deleting such apps, or carefully examining their privacy policies. The providers of apps and software may be located in and subject to the laws of states other than New Jersey, and other states may have less protective laws regarding your privacy rights.

The safest course is to avoid communicating online, by messaging apps, or by text message about anything you want to keep private.

2. Are there ways to keep my phone calls private?

Phone calls can be made more secure by using "burner" phones, calling from phones that are not tied to your identity, using *67 to block your caller ID, or using services like Google Voice or other apps that permit anonymous phone calls.

BASIC RIGHTS

3. Is abortion still legal in New Jersey?

Yes, abortion is still legal in New Jersey. Abortion is an independent and fundamental right protected by both the New Jersey Constitution and state legislation. The United States Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* does **not** diminish the right to an abortion in New Jersey.

4. Does New Jersey have abortion restrictions (waiting period, gestational limit, parental involvement, etc.)?

New Jersey places very few legal restrictions on abortion. There are no waiting period or parental involvement laws. Providers offer care based on each patient's specific circumstances, and if they are unable to provide care, they will usually refer the patient for other assistance.

5. I am under 18 years old. Can I get an abortion in New Jersey? Do I have to tell my parents or get parental consent for an abortion in New Jersey?

Yes, abortion is legal in New Jersey including for minors from out of state.

No, New Jersey law does not require you to tell your parents or get parental consent before having an abortion.

However, depending on the law of your home state, there may be risks to you or anyone who assists you in traveling across state lines, especially if you do not have permission from a parent to travel.

If you live in a state that has an abortion ban, you should talk to a lawyer about the potential consequences of traveling out of state to seek a legal abortion. In addition, because minors generally need parental consent to travel, if you are a minor seeking assistance from someone (even your parent or guardian) to travel to New Jersey for abortion care, you should talk to a lawyer about that, too. You can call the number below or contact the Repro Legal Helpline to try to get advice from a lawyer.

6. I live in a state with an abortion ban. What happens if someone in my state finds out I had an abortion in New Jersey? Can I get in legal trouble in my home state? Does New Jersey law protect me?

Many states with criminal bans on abortion do **not** seek to punish the person who gets the abortion, but instead target the health provider or others who help the patient get an abortion. To learn more about the laws of your home state, you can check these resources:

- Center for Reproductive Rights' State Law Tracker
- Guttmacher Institute Interactive Map
- New York Times' Tracker
- Washington Post's Tracker

State laws are changing rapidly. If you want to know more about the legal risks in a particular state, you can also contact the <u>Repro Legal Helpline</u>.

It is normally safe to travel to a state and engage in conduct that is legal in the state you are visiting. For example, people can travel to Las Vegas to gamble even if gambling is illegal in their home state, and their home state should not be able to punish them.

There is a risk, however, that the normal rules will not stop prosecutors in other states from trying to apply their existing criminal laws to conduct that is legal in the state where it occurs. We do not yet know how courts in other states will react to such law enforcement tactics.

As of the date of these FAQs, no state has passed a law that explicitly makes it a crime to provide an abortion in a state where it is legal to a resident of a state with a criminal ban. However, the laws in many states are rapidly changing, and there may be a risk to you or someone who is helping you get an abortion if you are a resident of a state with an abortion ban.

If there is a law that you believe may cause you trouble, you should consult with a lawyer. You can call the number below or contact the Repro Legal Helpline.

New Jersey law protects you only from repercussions in New Jersey—so long as you comply with state law, there will be no repercussions in New Jersey. In addition, New Jersey recently enacted a law that protects certain patient information regarding reproductive health services. This law cannot guarantee confidentiality, but it should protect your health information from disclosure to prosecutors and others from out of state in many circumstances. See Qs. 14, 15.

If you want to learn more about your reproductive rights at the national level, the Federal Department of Health and Human Services has published <u>useful information</u>.

ACCESS

7. Whom do I call to schedule an appointment? What clinics have the most availability?

Below are some resources that might be helpful to you. This list is not exhaustive.

<u>Abortion Finder</u>: AbortionFinder.org is a helpful national resource that allows those seeking an abortion to find a local provider. This resource indicates whether clinics provide abortion by medication, procedures, or both.

<u>I Need an A</u>: I Need an A is another national resource where you can search for a local abortion provider.

<u>Planned Parenthood</u>: Planned Parenthood has many clinics throughout New Jersey. As of the date of these FAQs, most locations are only offering abortions by medication.

<u>Cherry Hill Women's Center</u>: Cherry Hill Women's Center offers first- and second-trimester abortions.

8. Can someone help me schedule an appointment and make travel and logistical arrangements?

Maybe. Certain abortion funding organizations provide logistical and scheduling support. For additional information, visit <u>I Need an A</u>. You may also visit <u>Apiary for Practical Support</u> or <u>The Brigid Alliance</u> to find local practical support networks that provide assistance in making travel and logistical arrangements.

9. I need an abortion, but the wait time at all the New Jersey clinics is long. What are my options?

If you are in New Jersey and early in your pregnancy, you may be able to access abortion care via telemedicine. This is safe and approved by the FDA. Please see the resources in Q.7 to search for a provider who may be able offer telehealth services.

If you are seeking an in-clinic procedure and all locations in New Jersey have a long wait time, please also see national resources in Q.7 to determine if traveling to another state **where abortion is legal** is the best option for you.

PAYMENT

10. Can I use my health insurance to pay for an abortion in New Jersey?

As of the date of these FAQs, New Jersey law does not require health insurance policies to cover abortion or associated expenses, although the state is considering regulations that would impose a requirement. You'll need to call your health insurer or benefits administrator to find out if your insurance covers abortion and associated expenses.

You should know that using insurance to pay for an abortion can present a risk to confidentiality. A New Jersey-based health insurer must have your consent before disclosing your health information related to a legal abortion in New Jersey. But out-of-state insurers will be subject to the laws of other states, which could permit or require disclosure in response to a subpoena or court order. Moreover, even New Jersey-based insurers might contract with other companies that store electronic health data in other states, and those out-of-state entities are also subject to the laws and court orders of other states.

If you can afford it, the most confidential form of payment is cash (not an app like Apple Pay or Venmo, but actual cash).

11. Does NJ FamilyCare/Medicaid cover abortions for New Jersey residents?

Yes. NJ FamilyCare provides affordable health insurance for eligible New Jersey residents, including coverage related to pregnancy. All of the Medicaid health plans under NJ FamilyCare cover abortion services. New Jersey residents can check their eligibility by visiting the NJ FamilyCare website or the Department of Human Services website.

12. Is there any other financial help to pay for abortions and the associated costs if I have to travel?

Yes. Funding may be available to assist with several of the costs associated with getting an abortion, including the cost of the appointment, travel and lodging, and childcare. Below are some examples of resources that might be helpful to you. This list is not exhaustive.

If you need help paying, visit:

New Jersey Abortion Access Fund (NJAAF). Anyone who is pregnant, regardless of age, immigration status, and/or marital status can apply for funding through NJAAF. The only requirement is that the procedure is performed at one of the clinics in New Jersey that NJAAF works with.

<u>National Abortion Federation</u> (NAF) or call its hotline at 800-772-9100. NAF provides information on how to access abortion across the country. In addition, patients may be able to receive financial support to pay for their abortion, including the cost of travel.

<u>National Network of Abortion Funds</u> (NNAF), or the <u>National Network of Abortion Fundsaffiliated fund in your state</u>. NNAF organizes abortion funds and practical support organizations across the country to aid abortion seekers.

<u>Women's Reproductive Rights Assistance Project</u> (WRRAP). WRRAP provides abortion funding for patients across the country at certain provider locations. In addition to abortion funding, WRRAP also provides emergency contraception.

<u>Indigenous Women Rising</u> helps fund abortions in the United States and Canada for indigenous people. To use this funding, you must be able to prove membership in a tribal community.

PRIVACY

13. If I get an abortion from a New Jersey provider, will my health information about the abortion be confidential?

Maybe. It will depend on who is asking for the information, how they ask, whom they ask, and where the information is stored. The bottom line is that confidentiality of medical information is not guaranteed. See Qs.14–19, below.

14. Can health care providers, health plans, health insurers, and processors of health information in New Jersey disclose information related to my legal abortion in New Jersey?

Probably not. New Jersey recently enacted a <u>law</u> that increases protections for patient information relating to reproductive health services.

The new law covers health care providers, health plans and insurers, and/or processors of information received from a health care provider and/or health plan/insurer. These are collectively called "Covered Entities." Under the new law, Covered Entities in New Jersey are required to get the patient's written consent before disclosing information related to reproductive health services in any civil, legislative, or administrative proceeding. At or before the time reproductive health services are provided, Covered Entities must tell patients that they do **not** have to consent to the disclosure of their information.

The New Jersey law does not eliminate all risk, however. It is new and has not been tested in court. It does not prevent Covered Entities from sharing reproductive health information for the purpose of treatment, payment, or health care operations. For example, a reproductive health provider in New Jersey is still allowed to share your health information with your other health care providers. If you do not want your provider in New Jersey to share with other providers, you should ask them not to. Moreover, the new law does **not** protect reproductive health information that is in the possession of an entity other than a Covered Entity—such as a search engine, an app, bank or credit card companies, or servers that contain a person's text messages or other personal communications. If those entities decide to provide such information, they can do so. Entities in New Jersey cannot, however, be forced to do so. See Q.15.

15. Can public entities and employees in New Jersey cooperate in investigations into my legal abortion in New Jersey?

They should not. In some cases, an out-of-state prosecutor or private litigant might make a demand through a subpoena or court order for information about abortions that are legal in New Jersey. Subpoenas or court orders from outside New Jersey are generally only enforceable with the cooperation of the New Jersey courts. But another new law prohibits New Jersey public employees and entities, including New Jersey courts, from helping to enforce such an out-of-state subpoena or court order. New Jersey courts and prosecutors may not always be able to tell when an out-of-state investigation relates to a legal abortion, but if they can tell, they may not assist in the investigation. Without assistance from the New Jersey courts, out-of-state investigators will not be able to force anyone in New Jersey to comply with their demands for information.

To summarize, if a person from out of state seeks information in New Jersey related to reproductive health services that are legal in New Jersey:

- Covered Entities in New Jersey are prohibited from sharing such information without the patient's consent.
- Public entities and employees in New Jersey are prohibited from assisting with such an investigation.
- Entities in New Jersey that are not Covered Entities are **not** prohibited from sharing such information.
- Entities in New Jersey that are not Covered Entities but which do not want to share such information should be able to effectively resist complying with demands for information from those conducting the investigation.

16. Does it matter for protection of my health information whether I am a resident of New Jersey?

These protections make no distinction between patients who are residents of New Jersey and people who travel to New Jersey from other states to receive reproductive health services.

17. What if my health information is stored outside New Jersey?

If your health information is stored outside New Jersey, such as in a commercial database for sharing electronic medical records (for example, MyChart or Athena Health), those records may be subject to disclosure in other states based on those states' laws.

If your health information is shared with your other medical providers—such as your primary care physician in your home state—the information may be accessible through the provider in your home state.

18. Does HIPAA help me?

The Health Insurance Portability and Accountability Act ("HIPAA") is a federal law regarding the privacy of medical information. HIPAA generally requires that protected health information remain confidential, but HIPAA permits disclosure of such information, without the patient's consent, pursuant to court orders, subpoenas, and other similar legal process. Therefore, HIPAA will not protect the confidentiality of health information that is electronically stored in other states and is subject to lawful subpoenas or court orders in those states. The Federal Department of Health and Human Services has issued relevant guidance on HIPAA and its exceptions.

19. What if I pay for the abortion with a credit card, debit card, or electronic payment system such as Apple Pay or Venmo? Will my financial information be confidential?

The financial entities that hold information about your transactions are not "Covered Entities" (which include only health providers, health insurers or plans, or data processors for providers, insurers, or plans). Financial entities are therefore **not** covered by the New Jersey law that prevents Covered Entities from disclosing information about reproductive health services that are legal in New Jersey.

Public entities and employees in New Jersey are prohibited, however, from assisting in any out-of-state investigation into an abortion that is legal in New Jersey. This means that New Jersey courts will not help out-of-state prosecutors or others by demanding that any entity in New Jersey turn over your financial information related to a legal abortion.

Like other electronic records stored outside New Jersey, however, financial information stored in other states may be subject to disclosure demands under the laws of the states where they are stored.

If you can afford it, paying with actual cash is safer than paying with credit or debit cards or apps such as Apple Pay or Venmo.

You should consult with a lawyer if you are worried about privacy issues.

CRIMINAL AND CIVIL LIABILITY IN OTHER STATES FOR ABORTIONS IN NJ

20. What is the abortion law in my state?

If you are not sure what the law of your state is, you can check the resources in Q.6, which compile and describe state abortion laws.

21. If I am traveling to New Jersey for an abortion because the state where I live has a ban, can I be sued or prosecuted when I go back to my state?

Your home state should not be able to punish you for having an abortion that was legal in New Jersey, but there are no guarantees you'll be safe from attempts to punish you. See Q.6.

At this time, no state law allows private citizens to sue people for having abortions, but some states have passed laws that allow private citizens to sue abortion providers or others who help people from those states get abortions in violation of the laws of those states.

If you are traveling to New Jersey from a state that has imposed penalties for abortion, you should consult with a lawyer about the potential consequences of traveling out of state.

- If you want legal advice because you are concerned about arrest for abortion or have been contacted by law enforcement, you can securely contact the Repro Legal Helpline for legal advice, free legal representation, and referrals to defense attorneys.
- If you have been charged with a crime because of or related to an abortion, you or your attorney can contact the <u>Repro Legal Defense Fund</u> for bail assistance, case assistance, referrals to medical experts, and more.
- If you are under investigation or charged with a crime related to your pregnancy or any pregnancy outcome, or a child welfare action has been opened related to your pregnancy or any pregnancy outcome, you can contact National Advocates for Pregnant Women (NAPW), which may be able to help by providing criminal or family defense support or by connecting you to an attorney. NAPW can be reached confidentially by leaving a detailed message at 212-255-9252 or online.
- You can also call the number below.

22. I am not yet 18 years old. Are there special risks for me in traveling to New Jersey for an abortion?

So long as you are able to provide informed consent—meaning that you can understand the risks and benefits of the abortion and its alternatives—you can get a legal abortion in New Jersey. New Jersey law does not require you to notify or seek consent from a parent or guardian.

As a legal matter, though, people under 18 years old may need their parent's or guardian's permission to travel. In some states, a person (even possibly a parent or guardian) could face serious risks for helping you travel for an abortion in another state. *It is therefore especially important to consult with a lawyer if you are under 18 and you want to travel to another state for an abortion.* You can contact the Repro Legal Helpline to try to talk to a lawyer or call the number below.

If you cannot travel to New Jersey but plan to go to a different state, you may want to look at <u>If/When/How's Judicial Bypass Wiki</u> for information about your rights and a map of state laws affecting minors' access to abortion.

23. I can't travel to New Jersey. Can a New Jersey provider prescribe medication abortion via a telemedicine appointment and mail it to me in my home state? If my home state has a ban, could I get in trouble for taking the pills at home? Could the provider get in trouble?

The law of the state where you (the patient) are located will generally control a prescription by telemedicine. Therefore, if your state has a law prohibiting abortion, or prohibiting or restricting medication abortion through telemedicine, then receiving a prescription for medication abortion in your state from a provider in New Jersey may expose you and the provider to significant legal risk.

Abortion continues to be legal in many states in addition to New Jersey, and you may be able to find care closer to home in another state where abortion is legal. To search for abortion providers throughout the United States, visit <u>abortionfinder.org</u> or <u>I Need an A</u>.

If you want to learn more about access to medication abortion, you can check these websites: Plan C, Abortion on Demand, or Aid Access. For medical information on how to manage a medication abortion safely, these videos from Doctors Without Borders may be helpful. You may also want to contact the Repro Legal Helpline and check this information on your rights.

OUT-OF-STATE ABORTIONS FOR NEW JERSEY RESIDENTS

I'm from New Jersey but I'm staying/living right now in another state where abortion is illegal.

24. I need an abortion. What should I do?

The law of the state where you are located applies to your conduct in that state. You risk being criminally prosecuted if you are in a state where abortion is illegal, and the state allows prosecutions of patients. (Remember that many states criminalize only providers and helpers, not patients.) To learn more about your state's law, see the resources in Q.6.

If possible, you may want to travel to New Jersey or another state where abortion is legal. To search for abortion providers throughout the United States, visit <u>abortionfinder.org</u> or <u>I Need an A</u>.

25. I'm not yet eighteen. Can I travel to find a legal abortion?

There are special risks for minors. See Q.22.

26. Can a New Jersey provider prescribe me medication abortion via telehealth? Can they mail me the pills?

This involves significant risks. See Q.23.

27. What if I have an abortion in a state where it's illegal, and then I return to New Jersey? Am I safe? Can I be sent back to the hostile state for prosecution?

If you have an abortion in a state where it's illegal, returning to New Jersey cannot guarantee your safety. New Jersey recently enacted a <u>law</u> that protects people in certain circumstances from being "extradited." The police in a state with an abortion ban cannot cross state lines to arrest you in a different state. Instead, the state with the ban must use a process called "extradition" to have you taken into custody in a different state and then transferred to their state to face the charges against you.

Under the law, New Jersey will not extradite a person for providing, receiving, assisting in, supporting, or traveling to obtain reproductive health services that are legal in New Jersey. But the law is new and has not been tested in court. Moreover, the law has an exception. New Jersey will extradite a person who was in the state making the extradition demand at the time of the alleged crime and fled that state. Therefore, if a ban state charges you with a crime related to an abortion that allegedly took place there, and the ban state asks New Jersey to send you back there for criminal prosecution, New Jersey law will not prevent your extradition. If there is a demand for your extradition, you should immediately talk to a lawyer. You can call the number below.

28. What if I cause my own abortion without involving anyone else? Is that illegal in states that ban abortion?

That will depend on the law of the state where you were located when you managed your own abortion. To learn more, contact the <u>Repro Legal Helpline</u> and check this <u>information on your rights.</u>

29. If I have an abortion in a state with a ban, can I get in trouble with my school or employer?

In some states, employers and schools can discipline employees or students for having an abortion. Federal and state laws that prohibit discrimination on the basis of sex or pregnancy

might stop your employer or school from taking action against you, but you'd need to take your employer or school to court, and that can be a long and uncertain process.

You should know that, generally speaking, neither an employer nor a school has the right to access your personal health information, but some small employers with self-funded health plans may be able to learn of a particular employee's use of health insurance for reproductive services.

If you experience discrimination or harassment in employment, education, or healthcare related to obtaining an abortion, contact <u>National Women's Law Center Legal Network for Gender Equity</u>, which can assist you in finding legal assistance.

FAQs for Employers in New Jersey

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GENERAL INFORMATION

1. Is abortion still legal in NJ?

Yes, abortion is still legal in New Jersey. Abortion is an independent and fundamental right protected by both the New Jersey Constitution and state legislation.¹ The United States Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* does **not** diminish abortion rights and access in New Jersey.

2. What kinds of expenses do people seeking abortion face?

Abortion-related medical and non-medical expenses may present a serious barrier to accessing care, particularly for lower-wage workers in states where abortion is banned or restricted, who may need to travel long distances to get a legal abortion. According to the <u>Henry J. Kaiser Family Foundation</u>, the majority of self-pay, first trimester abortions cost about \$600.² Related expenses may include airfare, rental car, gas, lodging, meals, and childcare, and these costs may be doubled if the patient needs to travel with a companion. Non-medical expenses may total thousands of dollars, making abortion unaffordable for many people.³ The Federal

N.J.S.A. § 10:7-1(a) ("[T]he New Jersey Supreme Court has recognized that the right to reproductive choice is a fundamental right enshrined in the State Constitution, that this right is independent of the United States Constitution"); N.J.S.A. § 10:7-2(a) ("Every individual present in the State, including, but not limited to, an individual who is under State control or supervision, shall have the fundamental right to . . . choose whether to carry a pregnancy, to give birth, or to terminate a pregnancy. The New Jersey Constitution recognizes the fundamental nature of the right to reproductive choice, including the right to . . . terminate a pregnancy"); *Right to Choose v. Byrne*, 91 N.J. 287, 306 (1982) (holding that people have a "fundamental right" to make "one of the most intimate decisions in human experience, the choice to terminate a pregnancy or bear a child"); *Planned Parenthood of Cent. N.J. v. Farmer*, 165 N.J. 609, 612–13 (2000) (same).

² KFF, Employer Coverage of Travel Costs for Out-of-State Abortion (May 16, 2022), https://www.kff.org/policy-watch/employer-coverage-travel-costs-out-of-state-abortion/; see also Business Insider, Gas, Food, and a Hotel: Americans Seeking An Abortion Out of State Already Shell Out Up to \$10,000 for the Procedure (June 24, 2022), https://www.businessinsider.com/abortion-costs-roe-v-wade-out-of-state-supreme-court-2022-5.

³ Business Insider, *supra* note 2; *see also* Fed. Res. Bd., *Economic Well-Being of U.S. Households in 2020 – May 2021*, https://www.federalreserve.gov/publications/2021-economic-well-being-of-us-households-in-2020-dealing-with-unexpected-expenses.htm.

Reserve Board reports that 35% of Americans do not have sufficient cash, savings, or credit to cover a \$400 emergency expense.⁴

POTENTIAL LIABILITY

3. What kind of legal liability may a New Jersey employer face if it pays for out-of-state employees' travel to New Jersey for abortion care?

New Jersey employers that are considering paying for out-of-state employees to travel to New Jersey for abortion care should **consult a lawyer** to assess potential legal risks. It remains unclear how states with abortion bans or restrictions ("ban states") will seek to enforce existing criminal prohibitions on "aiding and abetting" or otherwise assisting their residents in obtaining abortions, whether ban states will enact laws that expressly punish assisting a patient to travel for an abortion, and how courts will respond to the extraterritorial application of such laws. It is also unclear whether courts will entertain cross-state civil suits under laws that purport to authorize private citizens to sue people who help others obtain abortions.

For an overview of state abortion laws, you can check these resources:

- Center for Reproductive Rights' State Law Tracker
- Guttmacher Institute Interactive Map
- New York Times' Tracker
- Washington Post's Tracker

Criminal and civil liability exposure depends on various factors, including the states where your employees are located and whether your company offers a self-insured plan (subject to the federal Employee Retirement Income Security Act of 1974, known as "ERISA") or a fully insured plan regulated by state law. An employer that offers abortion care and medical travel benefits through an ERISA plan may be less exposed to potential civil causes of action brought under state laws because of ERISA's broad conflict preemption provisions.⁵

EMPLOYEE SUPPORT

4. What kind of support are employers offering employees who need to travel for an abortion?

With federal protection for abortion eliminated, many employers are considering how they can assist employees who live in states where access to abortion is not available. This unofficial

⁴ Fed. Res. Bd., *supra* note 3.

⁵ See Section 514(a) of ERISA, codified at 29 U.S.C. 1144(a); see also Considerations for Employers and Employer Plan Sponsors Related to Potential Changes in the Effect of Roe v. Wade Morgan Lewis (May 6, 2022), https://www.morganlewis.com/pubs/2022/05/considerations-for-employers-and-employer-plan-sponsors-related-to-potential-changes-in-the-effect-of-roe-v-wade.

⁶ Andrew E. Graw, Julie Levinson Werner, and Batool T. Banker, *Employer-Paid Travel Assistance for Interstate Abortion Access*, Lowenstein Sandler (June 29, 2022),

<u>database</u> tracks responses from some large employers, including company statements and policies on paying travel costs and providing paid time off.

Employers who wish to expand benefits should consult with an employee benefits lawyer regarding the best way to structure new or expanded employee benefits (*e.g.*, medical, mental health, travel, childcare, paid time off, and legal services benefits). Employers may also want to seek legal counsel on how best to protect the privacy of employees who use the expanded benefits.⁷

As a starting point, some employers are conducting a self-audit to identify what medical, travel, paid time off, and other benefits their current policies cover; whether their current benefit plan imposes obstacles to timely and affordable abortion care (such as high deductibles and network provider limitations); and whether benefits should be expanded to promote health care access in general. Employers with offices in states that ban abortion may want to consider employee relocation and remote work policies for employees who wish to move out of such states.

5. What are the tax implications of providing these benefits?

Unless an employer provides a benefit through a flexible spending account (FSA), health savings account (HSA), or a health reimbursement account (HRA), paid benefits provided by an employer generally will be deemed taxable income to the employee under Internal Revenue Code Section 61. Accordingly, employers will be responsible for withholding employment taxes on benefit payments.

6. Where can I learn more?

We share this resource as plain language guidance for NJ employers. Various law firms and employee benefits consultants have published detailed articles on legal compliance and benefit structuring options which you may wish to review. Some of these articles are: Employer-Paid Travel Assistance for Interstate Abortion Access (Lowenstein Sandler, June 29, 2022); Impact of Dobbs v. Jackson Women's Health Organization for Employer-Provided Health Benefits (Ropes & Gray, June 27, 2022); Effect of Roe v. Wade (Morgan Lewis, May 6, 2022).

https://www.lowenstein.com/news-insights/publications/client-alerts/employer-paid-travel-assistance-for-interstate-abortion-access-eben-employment.

⁷ Various benefit structure considerations are addressed in the Andrew E. Graw article, *supra* note 6.

CONSUMER ALERT Crisis Pregnancy Centers

consumer*alert*

WARNING: Crisis Pregnancy Centers (CPCs) do NOT provide abortion care. CPCs are organizations that seek to prevent people from accessing comprehensive reproductive health care, including abortion care and contraception. Here's what you need to know about CPCs.

Your right to an abortion is protected in New Jersey. You have the right to truthful, unbiased, and medically accurate health information about abortion care and where to access such care. If you are pregnant, consult with a licensed health care provider to understand your options for abortion care and other reproductive health care services. Need help finding a provider? See the resources identified under "How Can I Find an Abortion Provider."

WHAT IS A CRISIS PREGNANCY CENTER?

Crisis Pregnancy Centers try to convince pregnant people not to have abortions. CPCs may appear to be reproductive health care clinics, but they do not provide abortion care or provide referrals for abortion care, contraception, or other reproductive health care.

Many CPCs do not provide any health care at all, despite suggesting to the public that they do. In addition, many CPCs are not licensed medical facilities and do not employ licensed medical professionals, which means that CPC staff likely are not required to keep your health information private or follow medical ethics rules and standards of care. CPCs may also provide false or misleading information about abortion—including the physical and mental health effects of abortion—to deter people from choosing abortion.

Some CPCs offer non-diagnostic ultrasounds, which may be performed by an unlicensed person who may not be qualified to provide that service. This non-diagnostic ultrasound may provide inaccurate or misleading results, including about how far along you are in your pregnancy. Only a licensed health care professional can accurately tell you how many weeks pregnant you are.

HOW CAN I SPOT A CRISIS PREGNANCY CENTER?

A Crisis Pregnancy Center may:

- Be a website, a call center, an app, or a physical location that looks like or is located near a clinic or doctor's office.
- Have a name that is similar to that of a health care provider, including words like "care," "health," "pregnancy," "resource," and "choice." (Note that many CPCs do not call themselves "crisis pregnancy centers"; nor do they use that term in advertising.)
- Offer free services (including pregnancy tests, ultrasounds, and adoption information) or supplies (including diapers and baby clothes) to individuals seeking abortion or reproductive health care services.
- Offer limited "counseling" services without providing complete or accurate information regarding all options for reproductive health care, including abortion.
- Postpone or reschedule appointments to delay individuals' access to abortion care.
- Pressure individuals to delay an abortion or continue a pregnancy, including by providing false or misleading information about the safety and legality of abortion care.

A facility may be a Crisis Pregnancy Center even if it:

- Has staff and volunteers who wear medical attire and collect personal and health information.
- Contains examination rooms with medical equipment (like an ultrasound machine) and supplies.

Continued

800-242-5846 > New Jersey Division of Consumer Affairs www.NJConsumerAffairs.gov



WHAT QUESTIONS SHOULD I ASK?

The New Jersey Division of Consumer Affairs recommends that individuals seeking an abortion or other reproductive health care services conduct their own research to determine what type of care is best and where to go for it. Look at reviews of the center and look at its website to see if comprehensive pregnancy-related services are offered. If staff are unable or unwilling to answer your questions, consider seeking treatment elsewhere. Be cautious of any attempts by the center to delay or dissuade you from the services that you are seeking. It is critical that you have timely access to care when you need it. When you arrive for your appointment, make sure you are in the right place, as many CPCs are located near clinics that provide abortion care.

If you are considering abortion and would like to be sure that you are not contacting a Crisis Pregnancy Center, here are some questions that you can ask:

- Does this center provide abortions? If so, what type (medication, surgical procedures)?
- If you don't provide abortion care yourselves, do you provide referrals to a provider where people can find abortion care?
- If I come in for a visit, will I be seen by a licensed medical professional? If so, what kind of licensed medical professional (doctor, nurse, midwife, etc.)?
- What services do you provide (for example, contraception, STD testing and treatment, ultrasound)?
- How much does treatment cost?
- Does the center accept health insurance or Medicaid?
- How will my health information and the services provided by this center be protected and kept private?
- Is the facility licensed? If so, what type of license?

You can check the status of a health care provider's license at https://newjersey.mylicense.com/verification. A listing of licensed health care facilities can be found at https://healthapps.state.nj.us/facilities/acSearch.aspx.

The Division of Consumer Affairs also recommends that health care professionals and social service organizations exercise caution so as to avoid unknowingly referring individuals seeking comprehensive reproductive health care or abortion care to a CPC.

WHAT SHOULD I DO IF I'M UNSURE ABOUT OR UNCOMFORTABLE WITH THE CARE THAT I AM RECEIVING?

You should leave. If at any point you realize or suspect that you are at a CPC and want to leave, it is generally your right to do so. You are under no obligation to a CPC or its staff.

HOW CAN I FIND AN ABORTION PROVIDER?

If you are seeking reproductive health care or access to abortion providers and services in New Jersey, the following external resources list licensed health care providers and services that may be available in your area:

- Planned Parenthood, which provides a list of abortion providers, in addition to reproductive health care services and educational resources https://www.plannedparenthood.org/.
- The National Abortion Federation, which provides a list of abortion providers https://prochoice.org/.
- **Abortion Finder**, which provides a list of abortion providers https://www.abortionfinder.org/.
- **Abortion Clinics Online**, which provides a list of abortion providers https://www.abortionclinics.com/state/new-jersey-abortion-clinics/.

If you think you may not be able to afford the cost of abortion care, talk to your health care or abortion provider about funding options that might be available to you.

HOW CAN I FILE A COMPLAINT?

If you believe you are a victim of fraudulent, deceptive, misleading, or unlawful conduct, please file a complaint with the New Jersey Division of Consumer Affairs at https://www.njconsumeraffairs.gov/Pages/Consumer-Complaints.aspx or 973-504-6200.

800-242-5846 • New Jersey Division of Consumer Affairs www.NJConsumerAffairs.gov



Raising the Bar: Defending Access to Abortion in New Jersey May 23, 2022, 12:30 – 2 p.m.

Panelist Biographies

PANELISTS

Dr. Kristyn Brandi, OB/GYN Physician

Dr. Kristyn Brandi MD MPH, the Darney-Landy Fellow at the American College of Obstetricians and Gynecologists, is an Obstetrician-Gynecologist with a fellowship training in Family Planning (contraception and abortion services). Dr. Brandi currently is a board member and the immediate past Board Chair of Physicians for Reproductive Health, sits on several subcommittees for the Society of Family Planning and is a founding member of Centering Equity, Racial and Cultural Literacy in Family Planning (CERCL-FP). She has published research on contraceptive coercion by doctors to patients seeking abortion. Her master's degree concentration focused on Health Law, Bioethics, and Human Rights, which she has focused her educational pursuits around abortion policy, contraceptive decision-making, and racial justice within medical education. She has been quoted in numerous articles on reproductive health and has written opeds around health care to such news outlets including the Washington Post.

Lauren Johnson, ACLU

Lauren Johnson is the Director of the Abortion Criminal Defense Initiative. She brings insights and experiences from her career as a public defender and civil rights advocate, fighting on behalf of communities and impacted individuals to challenge injustices within the criminal legal system. As a trial public defender, Lauren represented individuals charged with serious felonies at the Public Defender Service in Washington, DC (PDS).

Before joining PDS, she also represented clients charged with misdemeanors and felonies, and supervised law students as an E. Barrett Prettyman Fellow at Georgetown University Law Center's Criminal Justice Clinic. In addition to numerous bench and jury trials, Lauren has advocated for clients in a range of other contexts including parole, post conviction advocacy, civil litigation, and immigration matters. Lauren's experiences as a public defender informed her work as Senior Legal Counsel at the Justice Collaborative, where she worked to address systemic drivers of incarceration through community-focused campaign advocacy and policy development.

Most recently, as Senior Counsel at the NAACP Legal Defense and Educational Fund (LDF), Lauren led litigation and policy initiatives focused on creating lasting and systemic change in the criminal legal and education systems, including on behalf of those impacted by police violence, those harmed by unlawful police enforcement patterns and practices, and individuals charged with criminal offenses. Lauren received her J.D. from NYU School of Law, an LLM from Georgetown University Law Center, and her B.S. from Georgetown University.

Dean Kimberly Mutcherson, Rutgers University

Kimberly Mutcherson is Co-Dean and Professor of Law at Rutgers Law School in Camden. Dean Mutcherson is a reproductive justice scholar whose work sits at the intersection of bioethics, health law, and family. She has a particular focus on assisted reproduction, abortion, disability, and medical decision-making for pregnant women and children. Cambridge University Press released her edited volume, Feminist Judgments: Reproductive Justice Rewritten in 2020.

In 2021, Dean Mutcherson received the Association of American Law Schools inaugural Impact Award as a co-founder of the Law Deans Antiracist Clearinghouse Project and the M. Shanara Gilbert Human Rights Award from the Society of American Law Teachers for the same Project. She received the Center for Reproductive Rights Innovation in Scholarship Award in 2013, a Chancellor's Teaching Excellence Award in 2011, and the Women's Law Caucus Faculty Appreciation Award in 2011 & 2014.

Dean Mutcherson has been a Senior Fellow/Sabbatical Visitor at the Center for Gender and Sexuality Law at Columbia Law School and a Visiting Scholar at the Center for Bioethics at the University of Pennsylvania. She received her B.A. from the University of Pennsylvania and her J.D. from Columbia Law School. She also received the Kirkland and Ellis Fellowship for post-graduate public interest work upon her graduation from Columbia. Prior to joining the faculty at Rutgers, Dean Mutcherson was a consulting attorney at the Center for Reproductive Law and Policy (now the Center for Reproductive Rights) and a Staff Attorney at the HIV Law Project.

Catherine Weiss, Lowenstein LLP

Catherine Weiss is Chair of the Lowenstein Center for the Public Interest and a partner at Lowenstein Sandler. She both directs and participates in the firm's pro bono practice, which dedicates more than 20,000 hours each year to impact litigation, individual representation, and transactional work for nonprofits and microbusinesses.

Before joining Lowenstein Sandler, Catherine served as director of the Division of Public Interest Advocacy in the New Jersey Department of the Public Advocate. She supervised a staff of lawyers, policy analysts, and investigators working to protect and advance the public interest through a coordinated program of research, reporting, advocacy, and litigation.

Before entering state government, Catherine was Deputy Director of the Democracy Program at the Brennan Center for Justice at NYU School of Law where she worked principally on voting rights. For more than a dozen years previously, she worked in the national office of the ACLU, serving as director of the ACLU Reproductive Freedom Project from 1997-2002 and as its litigation director for the preceding five years. Catherine has also worked as a consultant to civil rights and human rights organizations and taught as an adjunct professor at Rutgers Law School in Newark.

She clerked for Judge Alvin Rubin of the United States Court of Appeals for the Fifth Circuit. She holds both a law degree and a master's degree in political science from Yale.

Jeanne LoCicero is the Legal Director of the American Civil Liberties Union of New Jersey. She supervises the litigation program and related advocacy of the ACLU-NJ's Legal Department and manages its 10+ person staff. Jeanne joined the ACLU-NJ as a staff attorney in 2004 and served as its Deputy Legal Director for ten years prior to becoming legal director in 2018. She has litigated and advocated in a wide range of civil rights and civil liberties cases, with a focus on prison conditions, racial equity, LGBTQ rights, women's rights, and reproductive health. She recently served on New Jersey's Transgender Equality Task Force, is a trustee of the Association of the Federal Bar of New Jersey, and serves on other legal and policy committees. Jeanne started her legal career as a legal fellow at the ACLU of Alabama after graduating with highest honors from Rutgers School of Law – Newark. She spent three years in private practice before joining the ACLU-NJ.