

Jill D. Moore, JD, MPH / September 2023





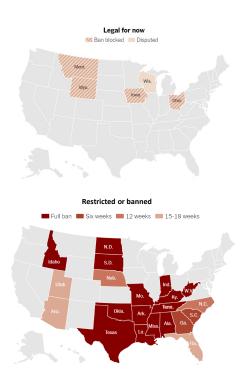
Dobbs v. Jackson Women's Health Organization

597 U.S. ___ (2022)

- In 2018, Mississippi adopted a law that banned abortion after 15 weeks of pregnancy. The law was challenged as a pre-viability abortion ban that was unconstitutional under previous Supreme Court cases. Roe v. Wade (1973); Planned Parenthood of Southeastern Pa. v. Casey (1992).
- In June 2022, the Supreme Court:
 - Upheld the Mississippi law by a 6-3 vote, and
 - Overruled Roe and Casey by a 5-4 vote.



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Effect of Dobbs

There is no longer a right to abortion under the U.S. Constitution.

States may adopt laws or state constitutional provisions that protect abortion, or that restrict or ban abortion.

Source of images: New York Times, Tracking Abortion Bans Across the Country, at https://www.nytimes.com/interactive/2022/us/abortion-laws-roe-v-wade.html (updated Sept. 19, 2023, accessed Sept. 21, 2023).



GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2023

SESSION LAW 2023-14 SENATE BILL 20

AN ACT TO MAKE VARIOUS CHANGES TO HEALTH CARE LAWS AND TO APPROPRIATE FUNDS FOR HEALTH CARE PROGRAMS.

The General Assembly of North Carolina enacts:

PART I. ABORTION LAW REVISIONS

SECTION 1.1. G.S. 14-45.1 is repealed.

SECTION 1.2. Article 1I of Chapter 90 of the General Statutes reads as rewritten:

"Article 1I.

"Woman's Right to Know Act. Abortion Laws.

"§ 90-21.80. Short title.

This act may be cited as the "Woman's Right to Know Act." "Abortion Laws."

"§ 90-21.81. Definitions.

The following definitions apply in this Article:

- Abortion. A surgical abortion or a medical abortion, as those terms are defined in this section, respectively.
- (1a) Abortion-inducing drug A medicine, drug or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination will, with reasonable likelihood, cause the death of the unborn child. This includes the off-label use of drugs such as mifepristone (Mifeprex), misoprostol (Cytotec), and methotrexate, approved by the United States Food and Drug Administration to induce abortions or known to have abortion-inducing properties, prescribed specifically with the intent of causing an abortion, whether or not there exists a diagnosed pregnancy at the time of prescription or dispensing, for the purposes of the woman taking the drugs at a later date to cause an abortion rather than contemporaneously with a clinically diagnosed pregnancy. This definition shall not include drugs that may be known to cause an abortion but are prescribed for other medical indications, such as chemotherapeutic agents and diagnostic drugs.
- (1b) Adverse event. Any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.
- (1c) Abortion. Surgical abortion. The use or prescription of any instrument, medicine, drug, or other substance instrument or device intentionally to terminate the pregnancy of a woman known to be pregnant with an intention other than to do any of the following:
 - Increase the probability of a live birth.
 - Preserve the life or health of the child.
 - c. Remove a dead, unborn child who died as the result of (i) natural causes in utero, (ii) accidental trauma, or (iii) a criminal assault on the pregnant woman or her unborn child which causes the premature termination of the pregnancy.



Key elements of new NC legislation

Definition of abortion

Lawful abortions & gestational week limits

Prohibited reasons for abortion

Consultation and consent requirements

Medication abortion

Other provisions

Definition of abortion (G.S. 90-21.81)

Basic definition: Abortion means the intentional termination of a known pregnancy:

- By instruments or devices ("surgical abortion"); or
- By medicines, drugs, or other substances ("medical abortion").

Exclusions: The definition does not include intentional terminations of pregnancy for any of the following reasons:

- To increase the probability of a live birth; or
- To preserve the life or health of the child; or
- To remove a fetus that has died as the result of natural causes, accidental trauma, or a criminal assault on the pregnant person or fetus; or
- To remove an ectopic pregnancy.

Lawful abortions & gestational week limits (G.S. 90-21.81B)

12 weeks

• During the first 12 weeks, unless for a prohibited reason

20 weeks

 Through the 20th week if the pregnancy was the result of rape or incest*

24 weeks

 During the first 24 weeks if the fetus has a life-limiting anomaly*

No week limit

• Life-threatening medical emergency*

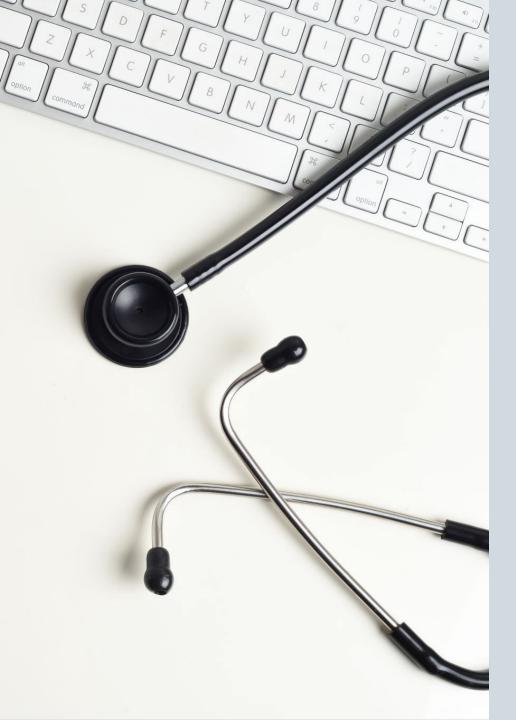
^{*} Terms in *italics* have statutory definitions (see definitions slides)

Prohibited reasons for abortion

(G.S. 90-21.121 as amended)

Abortion is not permitted if the person performing the abortion knows that the pregnant patient is seeking abortion either totally or partially because of:

- The fetus' actual or presumed race or racial makeup, or
- The fetus' sex, or
- The presence or presumed presence of Down Syndrome



Consultation and consent

(G.S. 90-21.81D; 90-21.82; 90-21.83; 90-21.83A)

72-hour advance in-person consultation (except in cases of medical emergency)

Specific information must be conveyed orally and in writing

Ultrasound imaging must be offered and in some cases is required

Consent forms must be created by NC DHHS and include certain elements (forms available at

https://www.ncdhhs.gov/assistance/north-carolina-reproductive-health-services)

Medication abortion

Additional requirements for providers (G.S. 90-21.83A; 90-21.83B)

- Physician must verify the probable gestational age of the fetus
- Physician must schedule a 7-14 day follow-up appointment for patient and make and document "all reasonable efforts" to ensure the patient returns
- The legislation requires ultrasound documentation of an intrauterine pregnancy before medication abortion, but this requirement has been enjoined while litigation is pending (*Planned Parenthood South Atlantic v. Stein*, case no. 1:23-CV-480)

Criminal infractions related to medication abortion (G.S. 14-44.1)

A new criminal law makes it an infraction punishable by a fine of up to \$5000 to do any of the following:

- Provide or advertise abortion-inducing drugs except as allowed by abortion laws
- Ship abortion-inducing drugs directly to pregnant people
- Provide website or other internet services solely to promote the sale of abortion-inducing drugs to be administered in violation of abortion laws

Other requirements

Physical presence of physician required

- Surgical abortion: during entire procedure (G.S. 90-21.82)
- Medical (medication) abortion: when first dose is administered (G.S. 90-21.83A)

Reporting, objection, and inspection requirements (G.S. 90-21.81C)

- Physician must record certain procedure information and findings
- NC DHHS must prescribe and collect certain reports
- NC DHHS must annually inspect clinics where abortions performed and publish inspection findings
- No health care provider may be required to participate in abortions

Facilities requirements

- Effective Oct. 1, abortions after 12 weeks gestation must be performed in hospital (this requirement is being challenged in Planned Parenthood South Atlantic v. Stein) (G.S. 90-21.82A)
- Requirements for the licensure of abortion clinics (G.S. Ch. 131E, Part 4A)



Medication abortion: FDA information

Regimen

• Initial dose of 200 mg mifepristone

• 800 mcg misoprostol 24-48 hours later

Contraindications

• Known or suspected ectopic pregnancy, IUD in place, certain other medical conditions or use of certain medications

Side effects

- Patients should anticipate uterine bleeding and cramping
- Nausea, vomiting, diarrhea, and headache are common

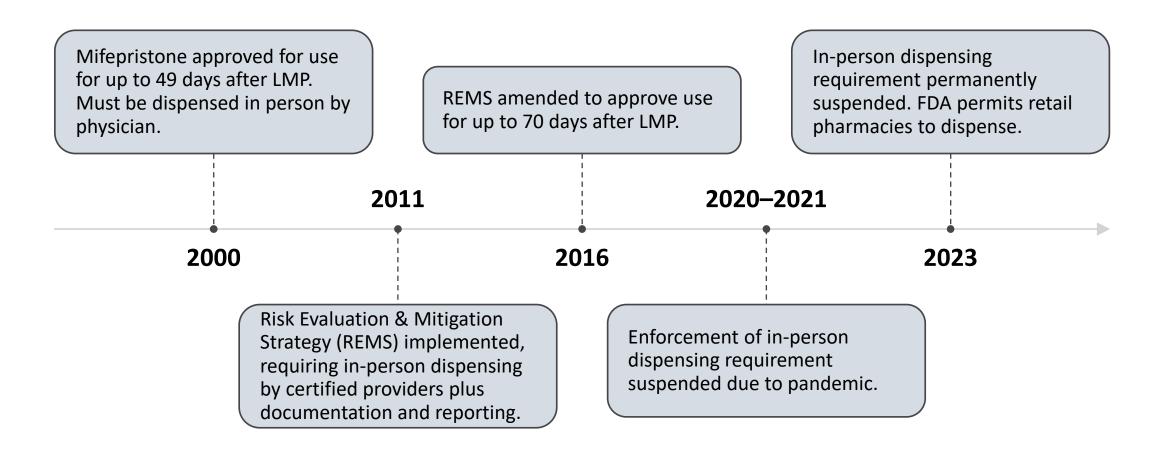
Warnings and precautions

- Sepsis and infection
- Excessive uterine bleeding

Serious adverse events (September 2000 -June 2022)

- 416 cases of blood loss requiring transfusion; 308 infections
- 28 deaths (9 sepsis, 2 ruptured ectopic pregnancies, 17 other)

Timeline: Mifepristone and the FDA



Alliance for Hippocratic Medicine v. U.S. Food & Drug Administration, 78 F.4th 210 (2023).

The plaintiffs in this case challenged the FDA's approval of mifepristone and sought a national injunction to take it off the market.

A federal district court invalidated the FDA's approval of mifepristone, but the decision was appealed promptly and never took effect.

The 5th Circuit Court of Appeals left the FDA's approval of mifepristone intact, but it concluded FDA must reinstate the old REMS rules, which precluded prescribing mifepristone by telemedicine or mailing it.

The 5th Circuit's ruling has been stayed by the Supreme Court and is not in effect, but the litigation is not over.





Mifepristone litigation status: September 22, 2023

The Fifth Circuit's decision has been stayed by the Supreme Court, which is expected to decide soon whether it will hear the case.

While the matter is pending, mifepristone remains an approved drug that may be used in states that allow medication abortion.

NC abortion law definitions (effective July 1, 2023)

G.S. 90-21.81

- Abortion means the intentional termination of a known pregnancy by instruments or devices ("surgical abortion") or medicines, drugs, or other substances ("medical abortion"). The definition of abortion specifically excludes the intentional termination of a pregnancy that is done for any of the following reasons:
 - To increase the probability of a live birth;
 - To preserve the life or health of the child;
 - To remove a dead, unborn child who died as the result of (i) natural causes in utero, (ii) accidental trauma, or (iii) a criminal assault on the pregnant woman or her unborn child which causes the premature termination of the pregnancy; or
 - To remove an ectopic pregnancy.
- Incest means criminally injurious conduct in the nature of the conduct described in G.S. 14-178 (carnal intercourse with a person's grandparent, grandchild, parent, child (biological or adopted), stepchild, sibling, half-sibling, aunt, uncle, nephew, or niece).

NC abortion law definitions cont. (effective July 1, 2023)

G.S. 90-21.81

- Life-limiting anomaly means the diagnosis by a qualified physician of a physical or genetic condition that (i) is defined as a life-limiting disorder by current medical evidence and (ii) is uniformly diagnosable.
- Medical emergency means a condition which necessitates abortion to avert the pregnant individual's death, or to
 avoid a serious risk of substantial and irreversible physical impairment of a major bodily function (not including
 psychological or emotional conditions or claims or diagnoses that the pregnant individual will commit suicide or
 irreversible self-harm).
- Rape means criminally injurious conduct in the nature of the conduct described in G.S. 14-27.21 (first-degree forcible rape), 14-27.22 (second-degree forcible rape), 14-27.23 (statutory rape of a child by an adult), 14-27.24 (first-degree statutory rape), and 14-27.25 (statutory rape of a person who is 15 years of age or younger).
- Unborn child means a member of the species homo sapiens, at any stage of development, who is carried in the womb.

References

Cases

Dobbs v. Jackson Women's Health Org., 597 U.S. __ (2022), slip opinion at https://www.supremecourt.gov/opinions/21pdf/19-1392 6j37.pdf.

Alliance for Hippocratic Medicine v. U.S. Food & Drug Administration, 2023 WL 2825871 (N.D.Tex., Apr. 7, 2023), stay granted in part by 2023 WL 2913725 (5th Cir., Apr. 12, 2023), stayed by 2023 WL 2942266 (Apr. 14, 2023), affirmed in part and vacated in part by 78 F.4th 210 (Aug. 16, 2023), petition for cert. filed (Sept. 12, 2023).

Legislation

N.C. Session Law 2023-14 (S 20). An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs. Enacted May 16, 2023, with various effective dates.

N.C. Session Law 2023-65 (H 190). An Act Making Technical, Conforming, and Other Modifications to Laws Pertaining to the Department of Health and Human Services and to Make Technical and Conforming Changes to S.L. 2023-14. Enacted June 29, 2023, with various effective dates.

Websites

N.C. Department of Health & Human Services, North Carolina Reproductive Health Services, at https://www.ncdhhs.gov/assistance/north-carolina-reproductive-health-services (accessed Sept. 22, 2023).

U.S. Food & Drug Administration, Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, at https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (accessed Sept. 22, 2023).

Blog Posts

Jill D. Moore, <u>Emergency Contraception vs. Medication Abortion: A Primer and Update on the FDA's Recent Actions</u> (December 28, 2022), available at canons.sog.unc.edu.

Jill D. Moore, North Carolina's Pending Abortion Legislation (May 8, 2023), available at canons.sog.unc.edu.

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