Paths to Protection:
Ways to Safeguard Access to Reproductive Care

Doctors for America

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Disclosures

- Expert witness retained by the American Civil Liberties Union in American College of Obstetricians and Gynecologists v. United States Food and Drug Administration, No. TDC-20-1320 (D. Md).

- Principal investigator on a collaborative study with the FDA, Risk Evaluation and Mitigation Strategy (REMS) Programs to Promote Appropriate Medication Use and Knowledge: A Multimodal Analysis (Contract Number 75F40120C0044).

Dobbs v. Jackson Women's Health Organization

- Mississippi Gestational Age Act
  - Restricted abortions in the state to up to 15 weeks gestation
  - Exceptions for medical emergency, severe fetal abnormality
- Original precedent: Roe v. Wade (1972)
  - Fundamental right to privacy encompasses abortion
  - Trimester framework: only minimal safeguards allowed in first
- Narrowing precedent: Planned Parenthood v. Casey (1992)
  - Upheld right, but instituted lower undue burden standard
  - Struck spousal notification requirement under Pennsylvania law but not parental consent, informed consent, and 24-hour waiting period requirements
- Decision
  - Overruled *Roe* and *Casey*, no constitutional right to abortion
  - States able to impose extreme restrictions and outright bans

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.

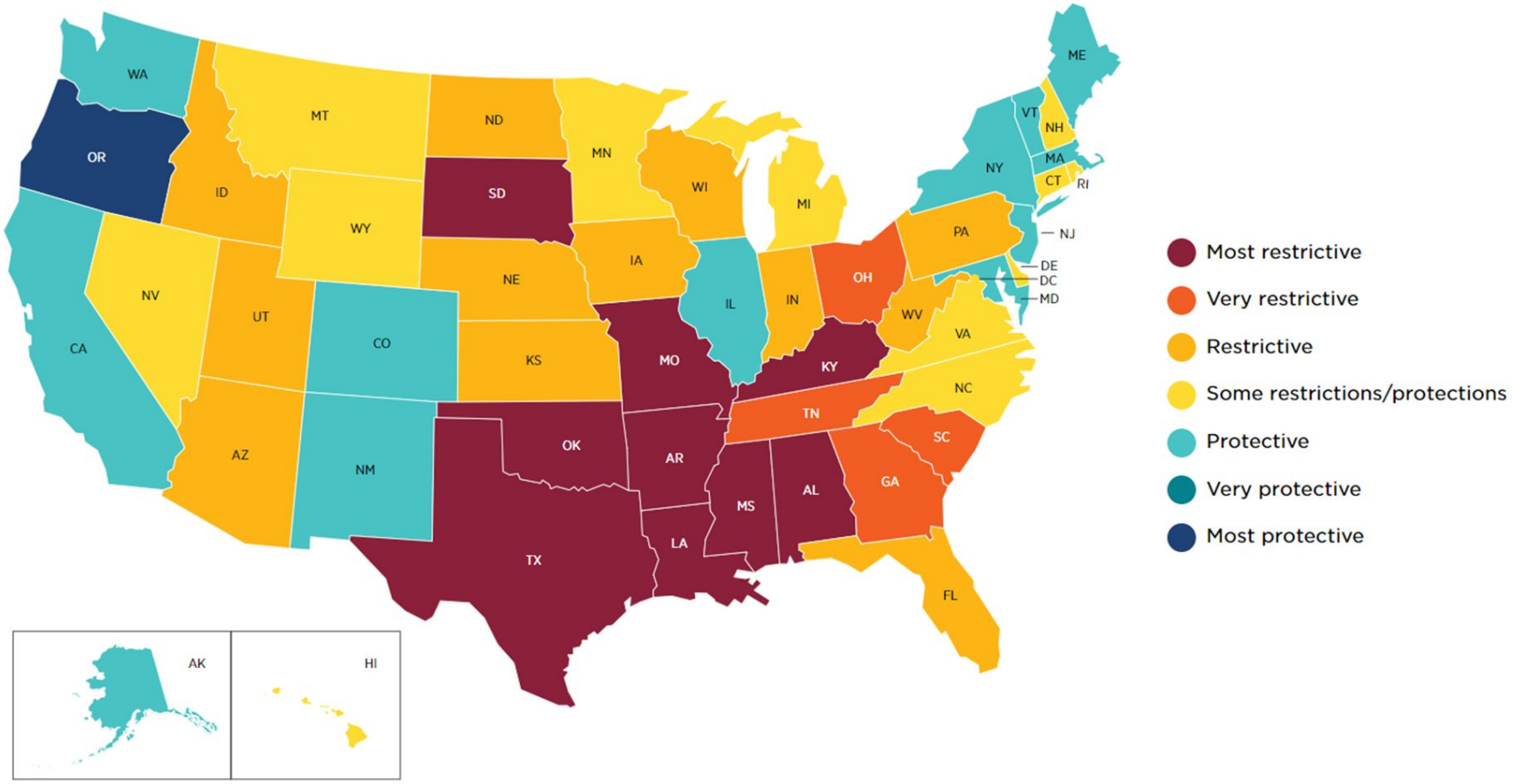
CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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.

State Landscape Post Dobbs



All or Most Abortions Banned

Explore the policy →

State Legislation	Introduced	Passed One Chamber	Passed Legislature	Enacted	Vetoed
	84	3	0	7	0

ıttmacher Institute. August 2022.

Consequences of State Restrictions

10-year-old rape victim forced to travel from Ohio to Indiana for abortion

Case places prominent anti-abortion figures in position of balancing rights of women and girls while defending restrictions

-Guardian. July 3, 2022.

'They're Just Going to Let Me Die?' One Woman's Abortion Odyssey

Madison Underwood was thrilled to learn she was pregnant. But when a rare defect in the developing fetus threatened her life, she was thrust into post-Roe chaos.

-New York Times. August 2, 2022.

Nebraska teen and mother facing charges in abortion-related case that involved obtaining their Facebook messages

-CNN. August 10, 2022.

HEALTH

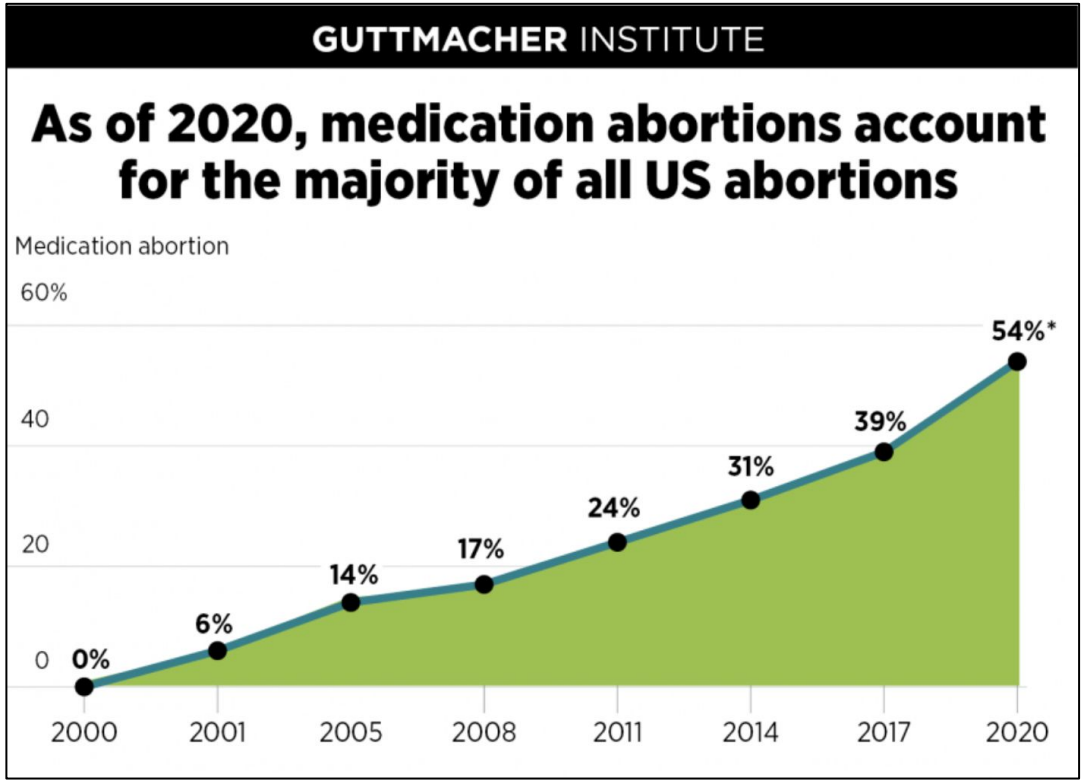
Confusion post-Roe spurs delays, denials for some lifesaving pregnancy care

Miscarriages, ectopic pregnancies and other common complications are now scrutinized, jeopardizing maternal health

-Washington Post. July 16, 2022.

Medication Abortion

- Increasingly used over surgical abortion
- Promise post-*Dobbs*: harder to police
- Common regimen: mifepristone + misoprostol
  - Efficacy: >95% up to 10 weeks gestation
- Mifepristone approval history
  - 1980: first synthesized (RU-486)
  - 1988: approved for use in France
  - 2000: FDA approval (manufacturer: Danco; brand-name: Mifeprex)
    - Original indication: "Mifeprex is indicated for the medical termination of intrauterine pregnancy **through 49 days' pregnancy**." (emphasis added)
  - 2016: revised indication
    - "MIFEPREX is a progestin antagonist indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy **through 70 days gestation**." (emphasis added)
  - 2019: first generic entry (manufacturer: GenBioPro); shared REMS approved



Mifepristone Safe Use Conditions

- Purported concerns: bleeding and infection
- Originally approved with safety program
  (which FDA could require because of approval pathway)
  - Restricted dispensing to physicians who attested to the ability to assess the duration of pregnancy, diagnose ectopic pregnancies, and provide surgical intervention or access to medical facilities able to provide blood transfusions in cases of incomplete abortion or severe bleeding
  - Required patients to receive a medication guide
  - Required patients and physicians to sign agreement forms
- In 2007, Congress granted FDA to require such program called REMS regardless of approval pathway when necessary to ensure that the benefits of use outweighed the risks
- Mifepristone deemed to have a REMS, but Danco submitted new proposed REMS that was approved in 2011
  - Same use conditions, but also three required physician visits

A Deeper Dive into Mifepristone Risks

Serious Adverse Reactions Reported in Women Following Administration of Mifepristone (oral) and Misoprostol (buccal) in U.S. and Non-US Clinical Studies

Adverse Reaction	US			Non-US		
	# of studies	Number of Evaluable Women	Range of frequency (%)	# of studies	Number of Evaluable Women	Range of frequency (%)
Transfusion	4	17,774	0.03-0.5%	3	12,134	0-0.1%
Sepsis	1	629	0.2%	1	11,155	<0.01%*
ER visit	2	1,043	2.9-4.6%	1	95	0
Hospitalization Related to Medical Abortion	3	14,339	0.04-0.6%	3	1,286	0-0.7%
Infection without sepsis	1	216	0	1	11,155	0.2%
Hemorrhage	NR	NR	NR	1	11,155	0.1%

NR= Not reported

* This outcome represents a single patient who experienced death related to sepsis.

-Current FDA drug labeling.

- 2016
  - FDA medical review: "Major adverse events including death, hospitalization, serious infection, bleeding requiring transfusion and ectopic pregnancy with the proposed regimen are reported rarely in the literature on over 30,000 patients. The rates, when noted, are exceedingly rare, generally far below 0.1% for any individual adverse event."
  - REMS changes: medication guide not needed, non-physicians could dispense (if satisfying criteria), number of required office visits reduced to one.

Narrow Challenge: ACOG v. FDA

- HHS and FDA pandemic policies
  - Promotion telemedicine
  - Suspension of
    - In-person visit requirement before being prescribed Schedule II narcotic
    - In-person visit requirements for clinical trials of investigational drugs
    - REMS requirements for laboratory testing and imaging
  - Mifepristone
    - Keeps in-person dispensing requirement
- Disposition
  - District Court: preliminary injunction granted
  - Circuit Court: refused to stay injunction
  - Supreme Court: stayed preliminary injunction
  - Resolution: FDA review of data and suspension of requirement during pandemic

Health

Judge: Women can get abortion pill without doctor visits

-Washington Post. 2020.

In summary, provided the other requirements of the Mifepristone REMS Program are met, and given that the in-person dispensing of mifepristone for medical termination of early pregnancy may present additional COVID-related risks to patients and healthcare personnel because it may involve a clinic visit solely for this purpose, CDER intends to exercise enforcement discretion during the COVID-19 PHE with respect to the in-person dispensing requirement of the Mifepristone REMS Program, including any in-person requirements that may be related to the Patient Agreement Form. Further, to the extent all of the other requirements of the Mifepristone REMS Program are met, CDER intends to exercise enforcement discretion during the COVID-19 PHE with respect to the dispensing of mifepristone through the mail either by or under the supervision of a certified prescriber, or through a mail-order pharmacy when such dispensing is done under the supervision of a certified prescriber.

-FDA Letter to ACOG. 2021.

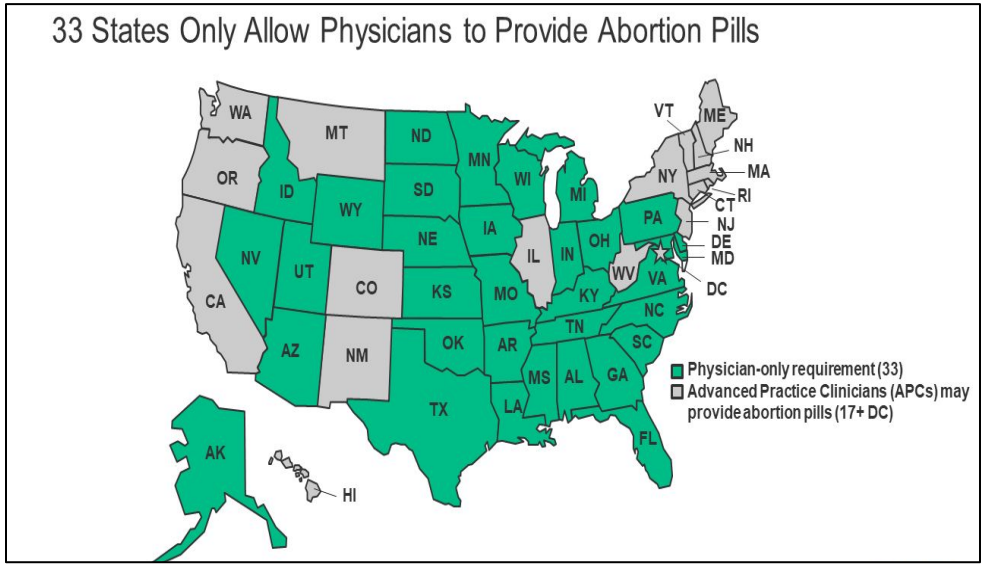
Broad Challenge: Chelius v. Azar

-Dr. Chelius.

- Issues
  - Whether the mifepristone REMS violates substantive due process rights?
  - Whether the mifepristone REMS violated equal protection rights?
  - Whether imposing the mifepristone REMS was a violation of the Administrative Procedures Act
    - One claim: action was arbitrary, capricious, and an abuse of discretion
- Plaintiff: Dr. Graham T. Chelius
  - Board-certified family medicine physician with focus in obstetrics
  - Chief Medical Officer for Hawaii Health Systems Corporations' Kaua'I region (population: 65,000)
  - Fear of inducing conflict among colleagues = does not provide abortion care
- Parties agreed to stay the litigation while FDA reviews the mifepristone REMS
- FDA agreed to change REMS in December 2021
  - Dispensing no longer limited to clinics, medical offices, and hospitals
  - Certification requirement for dispensing pharmacies and prescribing clinicians
  - Patient counseling requirement

State Laws Limiting Mifepristone Access

- Early versions: physician-only prescribing
- Just prior to Dobbs
  - Texas: requires physicians to ensure that a patient is no more than 7 weeks pregnant, despite FDA indication through 10 weeks of pregnancy
- Post-Dobbs may see
  - Severe restrictions on mifepristone access
    - Grounded in safety
    - Grounded in morality
  - Outright bans on medication abortion
  - More outright bans on all abortions



-Kaiser Family Foundation. 2020.

-Texas Star Tribune. 2021.

Federal Action to Increase Mifepristone Access

- Preemption challenges
  - Source of authority: Supremacy Clause of US Constitution
  - Types of preemption
    - Express preemption
    - Implied preemption
      - Impossibility preemption: precedent that includes stop-selling “solutions”
      - Obstacle preemption: in which state law thwarts the purpose of federal law
- Argument: state-required measures beyond those in the REMS upset the complex balancing between safety and burdens on the health care system that Congress delegated to FDA
  - More plausible when: state laws restricted to medication abortion, grounded in safety concerns
- REMS removal: multiple groups have called for elimination of the REMS altogether

Actions Physicians Can Take to Promote Reproductive Care

- Organize
- Create care networks
  - Facilitate out-of-state care (beware of coming, likely unconstitutional, state laws targeting this)
  - Expand potential prescribers
- Petition the administration to bring preemption challenges
- Petition FDA to remove the REMS on mifepristone
- Submit comments and offer testimony for proposed state laws
  - Adverse health impact on women
  - Exodus of providers
- Support reproductive rights proponents for office
- Run for office

Thank You!

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Statutory Factors in Determining Whether A REMS Needed

If the Secretary, in consultation with the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug, determines that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug, and informs the person who submits such application of such determination, then such person shall submit to the Secretary as part of such application a proposed risk evaluation and mitigation strategy. In making such a determination, the Secretary shall consider the following factors:

- The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug;
- The expected benefit of the drug with respect to the disease or condition;
- The seriousness of the disease or condition that is to be treated with the drug;
- Whether the drug is a new molecular entity;
- The expected or actual duration of treatment with the drug; and
- The estimated size of the population likely to use the drug.

-USC §355-1.