Nos. 25A1207, 25A1208

In the Supreme Court of the United States

DANCO LABORATORIES, LLC,

Applicant,

v.

LOUISIANA, ET AL.,

Respondents.

GENBIOPRO, INC.,

Applicant,

v.

LOUISIANA, ET AL.,

Respondents.

ON APPLICATIONS FOR STAY PENDING APPEAL AND FOR VACATUR OF STAY FROM THE U.S. COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR FAMILY RESEARCH COUNCIL AND MARTHA SHUPING, M.D., AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*

Family Research Council (FRC) is a Washington, D.C.-based nonprofit research and educational organization that seeks to advance faith, family, and freedom in public policy from a biblical worldview. FRC recognizes and respects the inherent dignity of every human life from conception until death and believes that the life of every human being is an intrinsic good, not something whose value is conditional based on its usefulness to others or to the state. Accordingly, FRC recognizes the inherent dignity of every woman, and supports the creation and use of proper medical ethics and standards designed to protect their health and well-being.*

Martha Shuping, M.D., graduated from Wake Forest University School of Medicine and completed her psychiatry residency at North Carolina Baptist Hospital. She has practiced psychiatry for 36 years, treating many patients who are survivors of intimate partner violence and human trafficking, and patients with PTSD related to trauma from reproductive losses including abortion. For many years, she has taught continuing education workshops to health professionals on IPV, human trafficking, PTSD, the intersection of mental health and reproductive issues, and medical ethics. She has an M.A. in Pastoral Ministry and conducts retreats for those desiring spiritual and emotional recovery after abortion. Dr. Shuping is an adjunct instructor in Psychology at Belmont Abbey College. In 1973, she served as a volunteer abortion counselor, helping women to access abortion, but now finds that life-affirming choices best serve women's health, well-being, and safety. Dr. Shuping desires that her patients, survivors of trauma, be protected from unsafe practices.

SUMMARY OF THE ARGUMENT

FDA's 2023 REMS has enabled a flood of abortion drugs to be released into society without any in-person interaction between the pregnant woman and a medical

* No counsel for a party authored this brief in whole or in part, and no person or entity, other than *amici curiae*, their members, or their counsel, made a monetary contribution to it.

professional. A single "nonprofit asynchronous telemedicine service" mailed 118,338 abortion drug packs between July 2023 and September 2024.[1] And the abortion drug manufacturers direct women to prescribers, while condemning the ruling below on the ground that "if this ruling is allowed to stand, everyone in America will lose access to mifepristone by mail or from a pharmacy."[2] Yet they simultaneously pretend that Louisiana lacks standing, because the connection between this lawsuit and abortion drug use—with resulting injuries to the State—is supposedly too uncertain. Their out-of-court actions belie their effort to shield FDA's unlawful action from review.

On the merits, FDA failed to consider the reality that many women will be coerced with these drugs if men, family members, and abusers can easily obtain them via remote means with no protection against coercion. Especially for women experiencing intimate partner violence (IPV), bypassing the substantial health benefits of in-person interaction with a medical professional places women at increased risk of harm to their health, well-being, and safety. Telemedicine abortions make it less likely that women experiencing IPV will be able to escape that cycle of violence. FDA's analysis never once acknowledged this reality, much less explained how its fully remote regime could protect women subject to coercion. The threat before thousands of women just like Rosalie Markezich is that their partners will coerce them to obtain and take drugs that will end their children's lives without their consent. Because FDA's action ignores this real threat, it is arbitrary and capricious.

Trying to justify FDA's action (while also ignoring the risk of coercion), the abortion drug manufacturers have relied on a recent "Special Communication" in a medical journal reviewing FOIA responses about FDA's action then pronouncing FDA's

[1] A. Aiken et al., *Provision of Abortion Medications Using Online Asynchronous Telemedicine Under Shield Laws in the US*, JAMA (Aug. 11, 2025), https://perma.cc/L4JU-AC7T.
[2] Democracy Forward, *Appeals Court Decision Will Limit Access to Medication Abortion Nationwide* (May 1, 2026), https://perma.cc/26GZ-XB77 (counsel for GenBioPro).

decision-making acceptable.[3] For many reasons, this study is facially deficient: it has no empirical foundation or scientific method and is based on documents in which everything pertaining to FDA's decision-making process was subject to redaction. The study also ignores the political pressure that led FDA to its action, including directives by President Biden and the HHS Secretary to expand abortions by mail.

Because FDA's 2023 REMS endangers women by ignoring the connection between remote abortions and coercion, the Court should deny the applications.

ARGUMENT

I. The drug manufacturers' own conduct confirms standing.

As the courts below found, Louisiana has standing. It has shown injuries to its sovereign and financial interests from FDA's unlawful action. And it "easily shows causation and redressability." *Louisiana v. FDA*, 2026 WL 1194924, at *5 (5th Cir. May 1, 2026). "As the district court explained, 'out-of-state medical providers' have responded to the 2023 REMS by 'expanding mifepristone access to pro-life states like Louisiana in ways that [are] entirely predictable.'" *Id.* The court said "[t]hat should surprise no one." *Id.*

It certainly comes as no surprise to the abortion drug manufacturers and their allies. Such expansion was the whole point of FDA's 2023 REMS. *See infra* p. 24. And the manufacturers intentionally aid out-of-state prescribers in sending abortion drugs to States like Louisiana. Indeed, at least in their out-of-court statements, the manufacturers argue that the decision below will limit the geographic availability of mifepristone. Such obvious, "predictable" reactions by "third parties" are enough "to establish" standing even when "a causal relation between injury and challenged action depends upon the decision of an independent third party" like prescribers. *California v. Texas*, 593 U.S. 659, 675 (2021). As this Court recently reiterated, "courts may make commonsense inferences when assessing Article III standing, including

[3] S. Dilek et al., *The US Food and Drug Administration's Regulation of Mifepristone*, JAMA (2026).

inferences about third party behavior." *First Choice Women's Res. Centers, Inc. v. Davenport*, 2026 WL 1153029, at *8 (U.S. Apr. 29, 2026) (internal quotation marks omitted). Standing's "causation requirement" merely "precludes *speculative* links—that is, where it is not sufficiently predictable how third parties would react to government action or cause downstream injury to plaintiffs." *Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367, 383 (2024) (emphasis added).

In court, the abortion drug manufacturers pretend that the connection between FDA's action and Louisiana's harms is too tenuous because it relies on third party prescriber behavior. *E.g.*, GenBioPro App. 25–27. "[T]hat is an odd argument for [the manufacturers] to advance." *Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100, 118 (2025). "After all, if invalidating the regulations would change nothing in the market, why are [the manufacturers] . . . defending the regulations?" *Id.* "[P]resumably," "they think that the regulations" "make a difference in the market." *Id.*

No speculation is needed for this conclusion. First, Danco and GenBioPro both aid and abet supposed third-party prescribers, providing extensive links on their websites to telehealth networks designed to facilitate unlawful mail-order abortions in States like Louisiana.[4] And after the decision below, the manufacturers, their counsel, and their allies have repeatedly said that staying the 2023 REMS will mean that "everyone in America will lose access to mifepristone by mail or from a pharmacy."[5] *See also* GenBioPro App. 35. They said that "this decision needlessly blocks people around the country from critical healthcare."[6] Planned Parenthood said that the decision below "means that it will be harder for everyone, everywhere to get an

[4] *See* Danco, *How Do I Get Mifeprex?*, https://perma.cc/6RUC-ABJW (linking to, *inter alia*, Plan C, whose tagline is "Abortion pills by mail in every state," https://perma.cc/6K85-SZDS); GenBioPro, *Patient Resources*, https://perma.cc/M554-47DF (listing "Trusted Providers" like "I Need An A").
[5] *Appeals Court Decision Will Limit Access*, *supra* note 2.
[6] Democracy Forward, *Democracy Forward Issues Statement on Urgent Supreme Court Applications to Protect Access to Mifepristone in the United States* (May 2, 2026), https://perma.cc/FHD6-PUKS.

abortion."[7] The ACLU said that "[t]his is going to affect patients' access to abortion and miscarriage care in every state,"[8] and that "[f]or countless people . . . losing a telemedicine option will mean losing access to this vital medication altogether."[9]

Under a banner reading "BREAKING: Court Upends Access to Medication Abortion," the Center for Reproductive Rights said that "[t]elehealth has been the last bridge to care for many seeking abortion" and called it a "lifeline, particularly for patients in states that restrict abortion."[10] Physicians for Reproductive Health said that "[a]*fter Dobbs*, over a quarter of patients who accessed abortion care did so . . . via telehealth"—bemoaning that after the decision below, "mifepristone via telehealth is no longer accessible for anyone seeking abortion care in the country."[11] The National Organization for Women said that "[m]ifepristone is an essential lifeline for people who live in abortion-ban states."[12]

"[A]bortion historian Mary Ziegler, a law professor at the University of California, Davis" said that "[t]elemedicine 'has been why people in abortion-ban states have been able to get access to abortion'": "'It's been the centerpiece of absolutely everything.'"[13] Her conclusion? "We're now going to see, I think in a way we haven't before, what the nation will look like when abortion bans are actually in effect."[14]

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[7] Planned Parenthood, *Planned Parenthood Action Fund Responds to Court Ruling That Restricts Access to Mifepristone Nationwide* (May 1, 2026), https://perma.cc/6NXP-RDZA.
[8] *Court Restricts Abortion Access Across the US by Blocking the Mailing of Mifepristone*, NPR (May 2, 2026), https://perma.cc/GV4F-U9NA.
[9] ACLU, *Federal Appeals Court Orders Nationwide Restrictions on Common Medication for Abortion and Miscarriage Care* (May 1, 2026), https://perma.cc/5FA7-KA7Z.
[10] Center for Reproductive Rights, *5th Circuit Limits Telehealth Provision of Abortion Pill* (May 1, 2026), https://perma.cc/FRU2-6YRC.
[11] Physicians for Reproductive Health, *Fifth Circuit Rules Mifepristone to be Dispensed In Person* (May 1, 2026), https://perma.cc/9YN3-V9XJ.
[12] NOW, *This Was a Blatantly Political Ruling That Endangers Women's Lives* (May 2, 2026), https://perma.cc/QH3N-9Y2Z.
[13] N. Martin, *A Right-Wing Court Just Moved to Choke Off Abortion by Mail*, Mother Jones (May 1, 2026), https://perma.cc/QNU2-YXR6.
[14] H. Schoenbaum et al., *What to Know About a Mifepristone Maker Asking the Supreme Court to Restore Access to the Pill by Mail*, PBS (May 2, 2026), https://perma.cc/7CCD-K9AT.

NPR said much the same: "telemedicine abortion" is "a big part of the reason why the overall number of abortions hasn't gone down at all nationally," so the decision below "severely restricts access in states with abortion bans."[15] Mother Jones said that the decision below "threatens to unravel one of the most important pathways to care post-*Dobbs*," as FDA's action "allowed blue-state telehealth providers to send mifepristone to thousands of patients every month in states where abortion is banned," "according to the most recent data from the #WeCount project."[16]

As the manufacturers' own conduct and these statements given within the last week reinforce, there is no question that Louisiana's challenge to FDA's mifepristone action satisfies the causation and redressability standing requirements.

II. Intimate partner violence often leads to coerced abortions of wanted children, causing psychological distress to mothers.

A. Intimate partner violence is widespread, and it worsens during pregnancy.

Turning to the merits of FDA's action, intimate partner violence is a widespread public health problem that encompasses physical, psychological, and sexual violence by one's intimate partner or former partner—but was glossed over by FDA.[17] "Approximately 324,000 pregnant women are abused each year in the United States."[18] "Approximately 1 in 4 women have been physically and/or sexually assaulted by a current or former partner."[19]

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[15] S. Simmons-Duffin, *A Federal Appeals Court Restricts Access to Abortion Pills via Telehealth*, NPR (May 2, 2026), https://perma.cc/CT2N-A4YS.
[16] Martin, *supra* note 13.
[17] American College of Obstetricians and Gynecologists, *Intimate Partner Violence*, Committee Opinion No. 518 (Feb. 2012, reaffirmed 2025), p. 1, http://tinyurl.com/mr3jvbew ("ACOG 2012").
[18] American College of Obstetricians and Gynecologists, *Reproductive and Sexual Coercion*, Committee Opinion No. 554 (Feb. 2013, reaffirmed 2025), p. 2, http://tinyurl.com/yb5s7fsx ("ACOG 2013").
[19] L. Chamberlain & R. Levenson, *Addressing Intimate Partner Violence: Reproductive and Sexual Coercion: A Guide for Obstetric, Gynecologic and Reproductive Health Care Settings* (3d ed. 2013), p. 8, https://perma.cc/GV64-CZ9B. This is a publication of American College of Obstetricians and Gynecologists jointly with Futures Without Violence.

There is increased risk of violence during pregnancy,[20] both as to frequency and severity.[21] In one study, interviews with women revealed that some of the men had admitted to beating the women to cause an abortion or miscarriage.[22]

Examples of men beating women to cause the death of the unborn child can be found in the news media. Timothy Kindle beat his girlfriend repeatedly over several months until finally killing the unborn baby. He admitted that he was intentionally trying to end the pregnancy.[23] "Injuring a female partner in a way that may cause a miscarriage" is an example of "reproductive coercion."[24]

B. Reproductive coercion often takes the form of coercing or forcing abortion of children wanted by their mothers.

"Reproductive coercion" is a form of IPV in which an abusive male partner seeks to control pregnancy outcomes by "violent acts" or "coercion to either continue or terminate the pregnancy."[25] "The relationship between violence and continuing or terminating a pregnancy is bidirectional" regarding coercion to continue a pregnancy or to end it.[26] Very often, reproductive coercion takes the form of coercing or forcing an abortion, leading to the abortion of wanted children—children who are desired by their mothers. "Women who want to continue their pregnancies may not be allowed to. Partners may also coerce women who do not want to terminate their pregnancies."[27]

In a U.S.-based study of IPV survivors experiencing reproductive coercion, some

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[20] A.M. Moore et al., *Male reproductive control of women who have experienced intimate partner violence in the United States*, 70 Social Science & Medicine 1737, 1737 (2010).
[21] J.C. Campbell et al., *Why Battering during Pregnancy?*, 4 AWHONNS Clinical Issues Perinatal Women's Health Nursing, 343, 345 (1993); ACOG 2012, *supra* note 17, at 2.
[22] Campbell et al., *supra* note 21, at 346.
[23] C. McRann, *Man accused of beating girlfriend, causing abortion*, Douglas Budget (Feb. 22, 2012), http://tinyurl.com/5n88d8xd.
[24] Chamberlain & Levenson, *supra* note 19, at 7.
[25] J.G. Silverman et al., *Male perpetration of intimate partner violence and involvement in abortions and abortion-related conflict*, 100 Am. J. Pub. Health 1415 (2010).
[26] Chamberlain & Levenson, *supra* note 19, at 14.
[27] *Id.*; ACOG 2013, *supra* note 18, at 1; Moore et al., *supra* note 20, at 1738, 1740; J.E. Hathaway et al*., Impact of partner abuse on women's reproductive lives*, 60 J. Am. Med. Women's Ass'n 42, 44 (2005).

women reported that their partners made violent threats to coerce the abortion. For example, one woman recounted that her partner told her, "If you don't get it done, I'm throwing you down the steps, or I'm doing something."[28]

Daniel Callahan, previously a pro-choice researcher with the Population Council, elaborated: "That men have long coerced women into unwanted abortion when it suits their purposes is well-known but rarely mentioned. Data reported by the Alan Guttmacher Institute indicate that some 30 percent of women have an abortion because someone else, not the woman, wants it."[29]

In a 2005 study of IPV survivors, a subset who had experienced reproductive coercion was asked to participate in a qualitative study. The authors discovered that "more than half of participants who reported limited reproductive control described being pressured by their male partners to terminate pregnancies."[30] They noted that no previous study had directly questioned women about coercion to abort and considered this a "potentially important reason for abortion."[31]

This study also revealed that pressure to abort "was extremely traumatic for some women and drove 1 woman to feel suicidal."[32] One woman stated: "My boyfriend was trying to push me to have an abortion . . . . He said, 'you won't keep that thing,' and he threatened to kill me. Then he said he would kill the child . . . . Several times I felt like I wanted to kill myself. I felt like if I had an abortion, I would have to kill

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[28] Moore et al., *supra* note 20, at 1740–41.
[29] D. Callahan, *An ethical challenge to prochoice advocates*, 117 Commonweal 681, 684 (1990).
[30] Hathaway et al., *supra* note 27, at 44. Reproductive coercion was not defined in a publication until Miller & Silverman (2010). Thus, the research of Hathaway et al. predates a formal definition of this problem and was groundbreaking in recognizing coerced abortion as an important area of study. The authors noted that the topic had not been addressed in "any recent reviews" and had not previously been a focus of study. Significantly, the study was published in the Journal of the American Medical Women's Association. The American Medical Women's Association has taken a strong abortion advocacy position since its founding in 1915, but nonetheless considered the topic of coerced abortion to be important. This study was also cited by Chamberlain & Levenson (2013), in a report jointly published by ACOG and Futures Without Violence, highlighting its importance.
[31] *Id.*
[32] *Id.*

myself."[33]

C. Coerced abortions of wanted children increase the risk of mental health problems including suicidal ideation in women.

Much evidence shows a connection between coerced abortions and mental health issues.

Evidence from the National Abortion Federation. Two textbooks include a table of risk factors that, if present before abortion, suggest the woman is at increased risk for adverse psychological reactions after the abortion. Both the 1999 and the 2009 textbook (currently in use) list "perceived coercion" as a risk factor for having adverse psychological reactions after the abortion.[34]

The recognition that some women experience coercion to have an abortion, with increased risk of adverse psychological reactions, indicates that some women wanted their children but aborted anyway. After all, there would not be coercion if the woman desired the abortion and freely chose it. That this is listed in both textbooks as a "risk factor" indicates that abortion providers know that some women are coerced, and that coercion to abort can harm the woman's mental health.

Both textbooks identify "commitment to the pregnancy" as another risk factor. Women who are committed to the pregnancy are at increased risk for adverse psychological reactions after abortion.[35]

Another pertinent risk factor is a history of sexual, physical, or emotional abuse.[36] Thus, some women experiencing IPV may face increased mental health risks from abortion associated with multiple factors.

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[33] *Id*.
[34] A. Baker et al., Informed consent, counseling, and patient preparation, *in* M. Paul et al., *A Clinician's Guide to Medical and Surgical Abortion*, p. 29 (1999) ("Baker 1999"); A. Baker et al., Informed consent, patient education and counseling, *in* M. Paul et al., *Management of unintended and abnormal pregnancy: Comprehensive abortion care*, p. 57 (2009) ("Baker 2009"). Both are chapters in books endorsed by the National Abortion Federation.
[35] Baker 1999, *supra* note 34, at 29; Baker 2009, *supra* note 34, at 57.
[36] Baker 2009, *supra* note 34, at 57.

Evidence from the American Psychological Association. The American Psychological Association's Task Force on Mental Health and Abortion stated in a 2008 report that there is increased risk to the woman's mental health when the pregnancy is "wanted or meaningful" to the woman but she aborts instead. This report stated that "feelings of commitment to the pregnancy predicted more negative postabortion responses."[37]

Evidence from recent research: the Add Health dataset. The National Longitudinal Study of Adolescent to Adult Health (abbreviated "Add Health") was created by congressional mandate with funding from 24 U.S. government agencies and private foundations.[38] The study was nationally representative and designed to be the most extensive analysis of the transition from adolescence to adulthood, providing a comprehensive resource for many health issues. More than 20,000 adolescents were enrolled in the study with more than 80% completion.[39]

This high-quality dataset has become a resource for more than 30,000 researchers and has led to more than 8,000 publications.[40] In 2016 and 2019, two important studies were published using this data.

A 13-year longitudinal study of pregnancy outcomes and mental health. A 2016 publication from this dataset, studying 8,005 women for over 13 years, showed that women having abortions had an increased risk of depression, anxiety, suicidal ideation, and multiple types of substance abuse, compared to women who gave birth. There were statistical controls implemented for many potentially confounding factors. The results were statistically significant.[41]

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[37] American Psychological Association, *Report of the Task Force on Mental Health and Abortion* (2008), https://perma.cc/6TR4-CD3L, pp. 11, 92.
[38] *About Add Health*, http://tinyurl.com/2ztbjrx3 (last visited Jan. 29, 2026).
[39] D.P. Sullins, *Affective and substance abuse disorders following abortion by pregnancy intention in the United States*, 9 Medicina 741, p. 4 (2019), http://tinyurl.com/2d2h3frw ("Sullins 2019").
[40] Add Health, *Publications*, http://tinyurl.com/2rc7jynm (last visited Jan. 29, 2026).
[41] D.P. Sullins, *Abortion, substance abuse and mental health in early adulthood*, Sage Open Medicine, p. 2, http://tinyurl.com/4z3pptfc (2016).

Another study using the same dataset in 2019 examined outcomes of wanted and unwanted pregnancies for multiple parameters, including anxiety, depression, suicidal ideation, and multiple forms of substance abuse. The most pertinent results showed that women who aborted one or more wanted pregnancies experienced a much higher risk of depression and suicidal ideation compared to women who gave birth. For women who had abortions, the relative risk for depression was 2.22 (more than double the risk), and for suicidal ideation was 3.44 (more than three times).[42]

Thus, women who are coerced by an abuser to abort a wanted child are more likely to experience a significant worsening of their mental health. The study's author also reported that "[c]ontrary to research claiming that unwanted pregnancy childbearing increases women's risk of mental health difficulties, in the Add Health data examined in the present study, women who gave birth to unwanted pregnancies consistently experienced lower risk of negative mental health compared to those who had an abortion."[43]

There is only limited research specifically on the psychological effects of chemical abortion. One study reported that seeing the deceased fetus was associated with more intrusive events, like nightmares, flashbacks, and unwanted thoughts related to the experience.[44] Dr. Shuping has clinical experience with women reporting having seen the fetus, and it is not surprising that seeing the fetus will occur more often with self-managed abortions at home as compared to surgical abortion; some women have had the experience of seeing their child in the toilet, and having to flush their deceased child.

The intrusion symptoms mentioned are symptoms of PTSD, a disorder that can

[42] Sullins 2019, *supra* note 39, at 1.
[43] *Id.* at 14.
[44] P. Slade et al., *A comparison of medical and surgical termination of pregnancy*, 105 British J. of Obstetrics & Gynaecology 1288, 1288 (1998).

be a long-lasting source of disability, and a source of great distress.[45] A textbook for abortion providers has also listed nightmares about babies as a potential adverse reaction to the abortion, though not specifically linked to chemical abortion.[46] But it is logical that with the intensity of the chemical abortion experience, including the horror of seeing one's deceased unborn child, one could be at greater risk for the intrusion symptoms of PTSD.

D. Intimate partner violence is associated with abortion and even more strongly with repeat abortion, indicating that abortions may perpetuate a repetitive cycle of abuse.

Although some abortion advocates claim that abortion is essential to prevent IPV survivors from being trapped in an abusive relationship, this is not borne out in research. In a systematic review with meta-analysis of 74 studies of IPV, nine studies showed women who reported IPV were more likely than the comparison group to have a history of multiple abortions.[47] "The highest quality study found that women presenting for a third TOP [termination of pregnancy] were over two and a half times more likely to have a history of physical or sexual violence than women presenting for their first."[48]

In a study of 1,318 Boston-area males that was included in the meta-analysis, perpetrators of IPV were more likely to have been involved in three *or more* pregnancies ending in abortion.[49]

This research indicates that the first two abortions did not end the violence or free women from abusive relationships. An "Editors Summary" stated, "Overall, the researchers' findings support the concept that violence can lead to pregnancy and to

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[45] American Psychiatric Association, *Diagnostic and statistical manual of mental disorders* (5th ed. 2013).
[46] Baker 1999, *supra* note 34.
[47] M. Hall et al., *Associations between intimate partner violence and termination of pregnancy*, 11 PLOS Medicine 1, 6 (2014).
[48] *Id.* (citing W.A. Fisher et al., *Characteristics of women undergoing repeat induced abortion*, 172 CMAJ 637, 640 (2005)).
[49] Silverman et al., *supra* note 25, at 1416.

subsequent termination of pregnancy, and that there may be a repetitive cycle of abuse and pregnancy."[50]

III. Confidential, private screening for IPV and provision of education and resources to end the violence are essential.

A. Routine screening and counseling for IPV and coercion are recommended or required.

The American College of Obstetricians and Gynecologists (ACOG) states: "Because of the known link between reproductive health and violence, health care providers should screen women and adolescent girls for intimate partner violence and reproductive and sexual coercion at periodic intervals," including new patient visits and at the first prenatal visit.[51] The first visit with an abortion provider would likely be a "new patient visit," thus an appropriate time to screen for IPV and coercion. Guidance from ACOG is clear that "all patients" should be screened.[52]

Others with similar recommendations for such screenings include the nonprofit organization Futures Without Violence (formerly the Family Violence Prevention Fund)[53] and the National Academy of Medicine (which published guidelines in 2011 under its former name, the Institute of Medicine, IOM).[54]

The U.S. Department of Health and Human Services and the Affordable Care Act require that "health insurance plans cover domestic violence screening and counseling as part of women's preventive services."[55]

It should be clear to anyone who is engaged in the practice of medicine that screening and counseling for IPV are not optional but should be a routine part of the provision of health care, especially when providing female reproductive healthcare.

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[50] Hall et al., *supra* note 47, at 25.
[51] ACOG 2013, *supra* note 18, at 1.
[52] ACOG 2012, *supra* note 17, at 3.
[53] Chamberlain & Levenson, *supra* note 19, at 3, 23, 37.
[54] *Id.* at 4.
[55] *Id.*

B. The main purpose of IPV screening is to provide education, resources, and interventions that will improve the health and safety of women.

During an office visit, patients can be offered information on safety planning, support services, and harm reduction strategies. One such clinic-based intervention was successful in reducing coercion by 71% among women experiencing IPV.[56] "Women in the intervention group were more likely to report ending a relationship because the relationship was unhealthy or . . . felt unsafe."[57] This example indicates that intervention can make a difference to improve well-being and safety.

Healthcare professionals can offer information on community resources such as mental health centers, crisis hotlines, shelters, legal aid, and other assistance.[58] A practical suggestion is to "offer the patient immediate and private access to an advocate in person or via phone."[59] The patient may feel unable to use her own phone if an abuser is monitoring her phone call log, but she might phone Legal Aid or the National Domestic Violence hotline from a medical office if given the opportunity.[60]

Education and discussion are considered essential even if the patient does not disclose abuse initially.[61] In the systematic review and meta-analysis of 74 studies of IPV, "women undergoing terminations of pregnancy welcomed the opportunity to disclose their experiences of intimate partner violence and to be offered help."[62]

C. Screening should be conducted in a private, confidential setting with the woman alone.

ACOG states: "Screen for IPV in a private and safe setting with the woman alone and not with her partner, friends, family, or caregiver."[63] If she were being abused, any of these people could be the abuser, so it is necessary to screen her alone.

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[56] ACOG 2013, *supra* note 18, at 2.
[57] *Id.*
[58] ACOG 2012, *supra* note 17, at 4.
[59] Chamberlain & Levenson, *supra* note 19, at 37.
[60] ACOG 2012, *supra* note 17, at 5.
[61] *Id.* at 3; ACOG 2013, *supra* note 18, at 3–4.
[62] Hall et al., *supra* note 47.
[63] ACOG 2012, *supra* note 17, at 3; ACOG 2013, *supra* note 18, at 3–4.

The National Abortion Federation also recognizes the necessity of confidentiality: "Confidentiality is of paramount concern to abortion patients. Providers must respect and protect their patients' right to confidentiality."[64] The National Abortion Federation states, "Providers have an ethical obligation to take reasonable precautions to keep their patients and staff safe."[65]

D. Telemedicine visits are not reliably confidential.

During telemedicine visits (when drugs are dispensed by mail), the perpetrator of abuse and coercion may be in the room with the patient, but off screen. This makes it impossible to do necessary screening for IPV and coercion, since the woman would not be free to discuss her situation honestly. It could be dangerous to the woman to be asked about IPV or coercion while the perpetrator of violence might be present and unseen.

Dr. Alan Braid, a physician who performs abortion, has testified that he never begins an abortion procedure until he has determined that the woman is "firm in her decision to proceed with the abortion."[66] But when telemedicine visits are done, it is impossible for an abortion provider to know whether the visit is truly private and confidential. If abortion providers previously have been able to have the degree of certainty that they claim, they can never have that certainty in any video visit today. A physician or other clinic staff conducting a pre-abortion assessment remotely will never know whether the woman on the screen, who affirms certainty of her intention to abort, is being coerced into the abortion of a loved and wanted child.

Due to the reality of reproductive coercion, and the association of IPV and coercion with abortion, what is certain is that some women will be in the position of asking for

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[64] National Abortion Federation, *Ethical Principles for Abortion Care* (2011), https://perma.cc/EMC9-B7G7.
[65] *Id.*
[66] Affidavit of Alan Braid, M.D., in Support of Plaintiff's Petition for Declaratory and Injunctive Relief ¶ 13, *Tulsa Women's Reproductive Clinic v. Hunter*, No. 2019-cv-2176 (Dist. Ct. Okla. Cnty. Sept. 23, 2019).

mifepristone under threat of violence, for the unwanted abortion of a loved and wanted child. Since ACOG has stated the need to screen for IPV in a private and safe setting, and at the same time there is a lack of privacy and lack of safety inherent in a video visit if a woman is experiencing IPV in her home, ACOG members are violating their own confidentiality policies in providing video visits to initiate an abortion. (Yet—like FDA—ACOG's medication abortion practice bulletin ignores the issue.[67]) Likewise, since the National Abortion Federation states the necessity of confidentiality, abortion providers who participate in the National Abortion Federation are seemingly violating their own ethics statement in providing video visits.

Beyond the mental health risks of aborting a wanted child under threat from an abusive partner, the abortion is more likely to perpetuate a cycle of repeated violence than to effect an escape from trauma. A woman who has been living with violence at home often is unaware of resources like free legal assistance, protection orders, women's shelters, and safety planning that could be vital to her escaping the violence. Unless she is seen in a healthcare facility where someone talks with her and provides this kind of information, she may never know what is possible. If she comes to a clinic where someone asks about her situation and offers help that she had never imagined, there is an opportunity for change in her life. Establishing a system that bypasses in-person screening and education is not giving an IPV survivor the help she needs and deserves.

As one author explained, "Interaction with the medical system is an opportunity for these women to be identified and helped, but ready availability of chemical abortion pills to their abusers will remove this opportunity for intervention."[68]

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[67] *See* American College of Obstetricians and Gynecologists, *Medication Abortion Up to 70 Days of Gestation*, https://perma.cc/C25E-6K96.

[68] I. Skop, *Chemical Abortion: Risks Posed by Changes in Supervision*, 27(2) J. of Am. Physicians and Surgeons 56, 58 (2022).

Dr. Shuping has treated patients who have experienced IPV. One woman had an abortion because she already had one child, and was afraid if she had a second child, she would be unable to protect both of them from the violence of her partner. But after the abortion, she experienced profound grief and distress, and sought emotional and spiritual recovery. By the time Dr. Shuping met her, she had left the abusive relationship. Had she left sooner, she might have had the child whose loss she was grieving. Had she been assisted with screening and education at an earlier time, she might have been equipped to use resources to achieve safety for herself and both of her children.

IV. Diversion of abortion pills obtained by mail can cause harm to others.

A. Abortion pills have been used to harm women and unborn children.

FDA REMS previously required that a woman seeking a mifepristone abortion receive the tablet in the presence of the abortion provider.[69] Administration in person by the provider ensures that the woman will take it at that time, for an abortion that she apparently intends, and that it will not be diverted to others.

Removal of the requirement for in-person administration of mifepristone in 2016, followed by the removal of the requirement for in-person dispensing in 2023, took away important safeguards for preventing diversion of abortion pills to those who may intend harm to others.

When the patient is at a distance from the abortion provider, the physician must rely on the patient to confirm that she had a positive pregnancy test. But the physician cannot be certain whether the woman on the screen is truly pregnant or is feigning pregnancy to obtain abortion pills for use by others. Any woman can say she is pregnant and desires an abortion to obtain pills for the purpose of diversion. "The

[69] *Id.*

potential for misuse and coercion is high when there is no way to verify who is consuming the drug."[70]

There are cases in which men have obtained mifepristone and/or misoprostol and put them in a beverage unknown to a girlfriend, "ex," or wife to force an abortion when the woman wanted the baby and the man did not. There have been cases reported in which other parties have attempted or succeeded in surreptitiously terminating another woman's pregnancy.

A few examples from news reports show that attempts to drug pregnant women to cause abortion are not a hypothetical risk. Stories about abortion drugs obtained in or from India demonstrate the consequences of loose drug regulations that can cause harm to others. No matter where or how the drugs were obtained in the cases below, current U.S. regulations make it easy for the problem to occur and to increase.

In October 2018, a Wisconsin man, Manishkumar Patel, was sentenced in Outagamie County, Wisconsin, to 22 years in prison. He was convicted of attempted first-degree intentional homicide of an unborn child after he slipped mifepristone, obtained from India by mail, into his girlfriend's drink.[71]

Jeffrey Smith, another Wisconsin man, pled guilty to attempted first-degree intentional homicide of an unborn child.[72] Smith purchased abortion pills in the mifepristone regimen illegally and attempted to kill his unborn child by putting mifepristone into his girlfriend's water bottle while she was 21 weeks pregnant. Smith had reportedly been urging his girlfriend to go to an abortion clinic, but she refused.[73]

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[70] *Id.*

[71] C. Robinson, *Man Gets 22 Years after Spiking Pregnant Girlfriend's Drink with Abortion-inducing Drug*, Associated Press (Oct. 11, 2018).

[72] S. Siewert, *Former Wausau-area man convicted of trying to kill unborn child with abortion pill*, Wausau Pilot & Review (Apr. 29, 2022), http://tinyurl.com/yyyyc3vu.

[73] K. Madden, *Grand Rapids man pleads not guilty to trying to poison Wausau woman to kill her unborn baby*, Wausau Daily Herald (June 12, 2018), http://tinyurl.com/mrhmp2p6. Police found the blister pack for the pills in the mifepristone regimen at Smith's home; only the first drug in the regimen, mifepristone, had been used to poison his girlfriend and her baby.

Mifepristone was originally approved in the U.S. for use only up to 49 days gestation, though it is now permitted by FDA up to 10 weeks.[74] But as the weeks of gestation increase, so do the risks of serious adverse effects, including hospitalization or surgery.[75] In this case, the woman did not immediately drink the water and later noticed the residue that led to investigation, apparently avoiding harm. Had his girlfriend ingested the intended dose, she might have experienced serious harm at 21 weeks' gestation. This example illustrates that when abortion pills are obtained and administered by deceptive means, there is the potential for grave harm to the woman as well as her unborn child.

Texas attorney Mason Herring was married but reportedly was romantically involved with someone else. Knowing that his wife was pregnant with his child, he obtained misoprostol, the second item in the two-drug abortion regimen, and repeatedly put it in her water glass intending for her to drink it unknowingly. He pled guilty to legal charges arising from this matter, now highly publicized, but his infant daughter was born 10 weeks prematurely and has suffered serious neurological complications and developmental delays.[76]

This example illustrates that men try to abort their unborn children, without knowledge of or interest in the safety of the mother, or the potential harm to the child. Other cases have led to deaths of unborn children. John Welden, a pre-med student, forged a prescription for misoprostol and tricked his girlfriend into taking it, causing the death of her wanted child. The tablets he used predated the pills-by-mail system now available.[77] The current regulations provide more opportunities "for traffickers,

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[74] Mifeprex (mifepristone), package insert, Danco Labs (Sept. 28, 2000).
[75] I.M. Spitz, *Early pregnancy termination with mifepristone and misoprostol in the United States*, 338 N. Eng. J. Med. 1241, 1246 (1998).
[76] D. Louallen, *Texas attorney sentenced to 6 months in alleged abortion attempt of wife's baby*, USA Today (Feb. 8, 2024), http://tinyurl.com/3d56twx5.
[77] L. Mungin, *Man pleads guilty to tricking pregnant girlfriend into taking abortion pill*, CNN (Sept. 10, 2013), http://tinyurl.com/4wp79p32.

domestic abusers, and men who do not want to become fathers to surreptitiously give abortion pills to women," since "these drugs can be so easily obtained by anyone."[78]

Research shows that women who are survivors of sex trafficking have reported having multiple abortions, including forced abortions. One woman reported seventeen abortions and said that some of them were forced.[79] This population of women may experience harm from their traffickers having easier access to abortion pills.

B. Regulation is needed to mitigate the risks of dangerous drugs; current REMS fail to mitigate mifepristone's unique risks.

Several classes of medications are tightly regulated for the dual purpose of preventing harm to the patient and reducing the risk of diversion that would lead to harm to others. These include narcotic pain medications, which have potential risks to patients and to others if diverted to them, as considered above. Another medication with dual risks, both safety and risk of diversion, is the psychiatric medication, Spravato,[80] which is provided under a REMS protocol. Spravato is associated with the potential for abuse and thus it can be administered only in a healthcare facility. For safety reasons, the patient is also required to stay for monitoring for two hours before going home. The medication cannot be taken home to avoid abuse by patient or diversion to others. Likewise, Zyprexa Relprevv requires administration at a healthcare facility with a three-hour period of monitoring afterward for safety reasons.[81]

Considering both the potential risks of diversion and the safety risks to abortion patients posed by using mifepristone and misoprostol for abortion, the current REMS do not provide mitigation of the known risks. On November 12, 2004, abortion drug manufacturer Danco itself felt the need to write a letter to emergency room directors raising serious safety concerns, including infection, sepsis, hemorrhage, and ectopic

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[78] Skop, *supra* note 68, at 58.
[79] L. Lederer & C. Wetzel, *Health Consequences of Sex Trafficking*, 23 Annals of Health Law 61, 72–74 (2014).
[80] Janssen Neuroscience, Spravato, full prescribing information (2023), http://tinyurl.com/73x5hzms.
[81] Eli Lilly & Co., Zyprexa Relprevv, full prescribing information (2009), http://tinyurl.com/3rsb76n4.

pregnancies.[82] Further, the possibility of an ectopic pregnancy continuing to develop after the patient has begun the mifepristone regimen should be a matter of significant concern.[83] As the Danco letter states:

> Physicians should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy since some of the expected symptoms of a medical abortion may be similar to those of a ruptured ectopic pregnancy.[84]

Ectopic pregnancy occurs in about 2% of all pregnancies.[85] Researchers at the Guttmacher Institute reported that there were 492,210 drug-induced abortions in 2020.[86] If only 1% of these represented women with ectopic pregnancies, that would be 4,922 women at risk for a ruptured ectopic pregnancy annually. If 2% is the accurate figure, then 9,844 women in this group would be at risk annually.

It is clear from Danco's letter and decades of experience that mifepristone is *not* a low-risk medication.[87] There is no question that current practices will lead to grave harm for some women, and that many women are at risk by the many deficiencies of the current REMS—though the REMS have never provided adequate mitigation.

V. JAMA's rehashing of FDA's positions lacks scientific legitimacy.

A recent article—relied on by the drug manufacturers here[88]—purports to show that FDA's abortion drug changes have been made "with the support of evidence and regulatory judgment."[89] This article, published as a "Special Communication" in the AMA's journal JAMA, involved several pro-abortion researchers filing FOIA requests for FDA documents, reading any non-redacted responses, assuming that whatever

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[82] Danco Letter to ER Directors, pp. 1–2 (Nov. 12, 2004), https://perma.cc/734R-LLSQ.
[83] In such instances, the screening for an ectopic pregnancy would have failed.
[84] Danco Letter, *supra* note 82, at 2.
[85] American College of Obstetricians and Gynecologists, *Tubal Ectopic Pregnancy*, at e91, https://perma.cc/HW5J-WSQF.
[86] R.K. Jones et al., *Abortion incidence and service availability in the United States, 2020*, 54 Perspectives on Sexual and Reproductive Health 128, 128 (2022).
[87] *See* K. Aultman et al., *Deaths and severe adverse events after the use of mifepristone as an abortifacient from September 2000 to February 2019*, 36 Issues L. & Med. 3, 3–4 (2021).
[88] Doc. 54-4, at 16 n.4.
[89] Dilek et al., *supra* note 3, at E6.

FDA staffers said was consistent with the science, then pronouncing approval when FDA sided with those staffers. This article is unserious. It lacks the basic criteria for a scientific publication and was instead an advocacy piece timed for a Senate hearing held two days after publication.

Unlike conventional scientific studies, this "Special Communication" does not begin with a falsifiable hypothesis, define outcome measures, justify assumptions, specify inclusion or exclusion criteria for evidence, or employ a systematic analytic framework. Instead, the authors retrospectively identify "key moments" and "key themes" in FDA's regulatory history, without providing a methodology for identifying these moments. Without the methodology, it is impossible to assess how the evidence was interpreted or what was excluded.

The article is rife with poor assumptions and analysis. To begin, the article relies entirely on agency FOIA responses that are necessarily incomplete. The article purports to draw sweeping conclusions about FDA's process, even as it acknowledges that some of its "key moments" are wholly obscured: "FDA extensively redacted documents describing the agency's internal deliberations regarding specific regulatory requirements under the REMS, and the details of this exchange are not available."[90] "[E]ntire pages were redacted," and any documents produced could not capture "internal discussion" that was not put on paper.[91]

The article boasts that "[i]nternal FDA documents offer a rare opportunity to examine how the agency made decisions over time about mifepristone."[92] But it seems blissfully unaware that the critical documents for its "analysis"—those bearing on how FDA made its decisions—would be subject to total redaction under the deliberative process privilege, which "shields from disclosure documents reflecting advisory

[90] *Id.* at E2.
[91] *Id.* at E6.
[92] *Id.* at E5.

opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated." *United States Fish & Wildlife Serv. v. Sierra Club, Inc.*, 592 U.S. 261, 267 (2021) (cleaned up); *see* 5 U.S.C. § 552(b)(5). Using documents shorn of all decisional material to "shed light on how regulatory decisions about mifepristone have been made"[93] borders on the absurd—especially given that the authors do not even acknowledge this core problem.

The article's poor assumptions don't end there. The article seems to assume that the views of "scientists in the FDA's review division"[94] are unbiased reflections of the scientific evidence—and that that evidence generally supports the abortion pill regime. Neither assumption is sound, much less defended in the article.

FDA's staffers are individuals with their own biases and inclinations—likely in favor of abortion[95]—and "scientists don't always follow the science themselves." *Whole Woman's Health v. Paxton*, 10 F.4th 430, 465 (5th Cir. 2021) (Ho, J., concurring). Indeed, contradicting the article's guesses about FDA staffers' motivations, Danco's own consultant has said that "FDA worked hard to increase access to mifepristone" but was limited by a desire to avoid congressional oversight.[96] FDA was so enthusiastic that it sometimes went beyond what Danco's application could support: "Danco sent in data to go through nine weeks, and FDA said, actually, we're going to go through ten weeks."[97] And "[i]t was the FDA that said, we're going to change 'doctor' to 'licensed healthcare provider,' and we're going to remove from the label the requirement that patients take the drug in clinic."[98] The article omits this information, which undermines its assumptions about FDA's "neutral" staffers.

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[93] *Id.* at E2.
[94] *Id.* at E4.
[95] *See, e.g.*, A. Frandell et al., *Abortion Rights: Perspectives of Academic Scientists in the United States*, 5(1) Women's Health Reports 602 (2024).
[96] C. Baker, *Abortion Pills: US History and Politics* 80 (2024).
[97] *Id.* at 82.
[98] *Id.*

The article also omits that FDA's consideration of chemical abortion drugs has always been intensely political. As Family Research Council has shown in detail, during FDA's original approval in 2000, "science, health and safety took a back seat to the bare-knuckles political tactics of the abortion industry and the Clinton administration."[99] Though the article mentions statements by the current HHS Secretary about a new evaluation[100]—statements outside the scope of the article's timeframe of analysis—it inexplicably omits the *many* statements preceding the 2023 FDA decision showing how political that decision was.

In 2022, on the day this Court decided *Dobbs v. Jackson Women's Health Organization*, President Biden "directed the Secretary of Health and Human Services to identify all ways to ensure that mifepristone is as widely accessible as possible," "including when prescribed through telehealth and sent by mail."[101] On the same day, the HHS Secretary "directed every part of my Department to do any and everything we can" to promote "access" to "medication abortion."[102] In a speech calling *Dobbs* "despicable," the Secretary pledged that "HHS will take steps to increase access to medication abortion."[103] "We will leave no stone unturned," the Secretary said, and "[a]ll options are on the table."[104] Then President Biden issued an executive order formally requiring HHS to seek ways "to protect and expand access to abortion care, including medication abortion."[105] Strangely, the JAMA article purporting to show

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[99] Brief *Amicus Curiae* of Family Research Council, *Alliance for Hippocratic Med. v. FDA*, No. 22-cv-223, 2023 WL 2974516 (Feb. 10, 2023).
[100] Dilek et al., *supra* note 3, at E6.
[101] White House, *FACT SHEET: President Biden Announces Actions In Light of Today's Supreme Court Decision on* Dobbs v. Jackson Women's Health Organization (June 24, 2022), https://perma.cc/66T6-BL87.
[102] U.S. Dep't of Health & Human Servs., *HHS Secretary Becerra's Statement on Supreme Court Ruling in* Dobbs v. Jackson Women's Health Organization (June 24, 2022), https://perma.cc/89AZ-RFL4.
[103] U.S. Dep't of Health & Human Servs., *Remarks by Secretary Xavier Becerra at the Press Conference in Response to President Biden's Directive following Overturning of* Roe v. Wade (June 28, 2022), https://perma.cc/KW6H-KF7D.
[104] *Id.*
[105] Exec. Order 14,076, 87 Fed. Reg. 42,053 (July 8, 2022).

that FDA's actions had nothing to do with politics omitted all this.

The JAMA article's "analysis" is deficient in many other ways. The article has no verifiable analytic framework. The authors simply plucked (redacted) FOIA responses out of a stack and engaged in some subjective qualitative weighing to analyze them. The authors rightly concede their interpretation of the documents "necessarily reflects [the authors'] judgments" and "may not fully capture . . . the influence of external pressures."[106] This was no reproducible scientific analysis.

What's more, none of the authors appears to have an expertise in interpreting FDA regulatory documents to assess its decision-making. The lead author, for instance, appears to be a program manager who received a master's in public health in 2024 and has no FDA experience. Unsurprisingly, the authors' "qualitative review" aligned with their ideological support for abortion: one author said in 2023 that claims against FDA's mifepristone action were "just not credible,"[107] while another wrote that "it is wrong for [courts] to override the highly specialized expertise, methodologies, and mandates of public health agencies and expert groups."[108] Of course, the authors are entitled to their opinions, and good research *can* be conducted by people with a viewpoint. But when the "research" is just "relate your feelings about documents," it is hardly surprising that FDA defenders approve of whatever FDA documents they happened to see.

CONCLUSION

For these reasons, the Court should deny the applications.

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[106] Dilek et al., *supra* note 3, at E6.
[107] S. Lupkin, *Here's What Really Happened During the Abortion Drug's Approval 24 Years Ago*, NPR (Mar. 26, 2024), https://perma.cc/3CJB-6YG7.
[108] E. MacKenzie et al., *Judicial Overreach is an Immediate Hazard to Already Precarious Public Health*, Stat (Apr. 20, 2023), https://perma.cc/UP9R-TFJX.

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