

No. 26-30203

United States Court of Appeals for the Fifth Circuit

STATE OF LOUISIANA, ET AL.,
PLAINTIFFS-APPELLANTS/CROSS-APPELLEES,

v.

FOOD & DRUG ADMINISTRATION, ET AL.,
DEFENDANTS-APPELLEES,

v.

GENBIOPRO, INC.,
INTERVENOR-APPELLEE/CROSS-APPELLANT,

v.

DANCO LABORATORIES, L.L.C.,
INTERVENOR-APPELLEE/CROSS-APPELLANT.

*APPEAL FROM THE U.S. DISTRICT COURT FOR THE WESTERN DISTRICT OF LOUISIANA,
NO. 26-CV-1491, HON. DAVID C. JOSEPH, PRESIDING*

**BRIEF OF FAMILY RESEARCH COUNCIL AND MARTHA SHUPING,
M.D., AS *AMICI CURIAE* SUPPORTING APPELLANTS**

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SUPPLEMENTAL CERTIFICATE OF INTERESTED PARTIES

State of Louisiana v. FDA, No. 26-30203:

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1, in addition to those listed in the briefs of the parties, have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

Amici: Family Research Council does not have a parent corporation and is not publicly held.

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June 22, 2026

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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.¹

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. 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

¹ All parties consented to this brief. No party's counsel authored this brief in whole or in part, and no person other than *amici* or their members or counsel contributed money to fund preparing or submitting it.

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.

INTRODUCTION

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 professional. A single “nonprofit asynchronous telemedicine service” mailed 118,338 abortion drug packs between July 2023 and September 2024.² And the abortion drug manufacturers direct women to prescribers, while condemning this Court’s stay 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.”³ 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.

² 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>.

³ Democracy Forward, *Appeals Court Decision Will Limit Access to Medication Abortion Nationwide* (May 1, 2026), <https://perma.cc/26GZ-XB77> (counsel for GenBioPro).

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.

ARGUMENT

I. The drug manufacturers' conduct confirms standing.

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*, 175 F.4th 310, 319 (5th Cir. 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.* This Court said “[t]hat should surprise no one.” *Id.*

It certainly comes as no surprise to the abortion drug manufacturers and their allies. First, such expansion was the whole point of FDA’s 2023 REMS. In 2022, on the day the Supreme 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.”⁴

What’s more, 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 staying the 2023 REMS 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 the Supreme Court recently reiterated, “courts may make commonsense inferences when assessing Article III standing, including inferences about third party behavior.”

⁴ 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>; see also Brief *Amicus Curiae* of Family Research Council, *Alliance for Hippocratic Med. v. FDA*, No. 22-cv-223, 2023 WL 2974516 (Feb. 10, 2023).

First Choice Women’s Res. Centers, Inc. v. Davenport, 146 S. Ct. 1114, 1125 (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. “[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. 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.⁵ And after the motions panel’s decision here, the manufacturers, their

⁵ 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”).

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.”⁶ They said that “this decision needlessly blocks people around the country from critical healthcare.”⁷ Planned Parenthood said that the stay “means that it will be harder for everyone, everywhere to get an abortion.”⁸

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.”⁹ 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 this Court’s prior decision, “mifepristone via telehealth is no longer accessible for anyone seeking abortion care in the country.”¹⁰

⁶ *Appeals Court Decision Will Limit Access*, *supra* note 3.

⁷ 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>.

⁸ Planned Parenthood, *Planned Parenthood Action Fund Responds to Court Ruling That Restricts Access to Mifepristone Nationwide* (May 1, 2026), <https://perma.cc/6NXP-RDZA>.

⁹ Center for Reproductive Rights, *5th Circuit Limits Telehealth Provision of Abortion Pill* (May 1, 2026), <https://perma.cc/FRU2-6YRC>.

¹⁰ Physicians for Reproductive Health, *Fifth Circuit Rules Mifepristone to be Dispensed In Person* (May 1, 2026), <https://perma.cc/9YN3-V9XJ>.

“[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.’”¹¹ 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.”¹²

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 stay “severely restricts access in states with abortion bans.”¹³ Mother Jones said that the stay “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.”¹⁴

¹¹ N. Martin, *A Right-Wing Court Just Moved to Choke Off Abortion by Mail*, Mother Jones (May 1, 2026), <https://perma.cc/QNU2-YXR6>.

¹² 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>.

¹³ S. Simmons-Duffin, *A Federal Appeals Court Restricts Access to Abortion Pills via Telehealth*, NPR (May 2, 2026), <https://perma.cc/CT2N-A4YS>.

¹⁴ Martin, *supra* note 11.

As the manufacturers’ own conduct and these recent statements 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.¹⁵ “Approximately 324,000 pregnant women are abused each year in the United States.”¹⁶ “Approximately 1 in 4 women have been physically and/or sexually assaulted by a current or former partner.”¹⁷

¹⁵ American College of Obstetricians and Gynecologists, *Intimate Partner Violence*, Committee Opinion No. 518 (Feb. 2012, reaffirmed 2025), p. 1, <http://tinyurl.com/mr3jvbw> (“ACOG 2012”).

¹⁶ 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”).

¹⁷ 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,¹⁸ both as to frequency and severity.¹⁹ In one study, interviews with women revealed that some of the men had admitted to beating the women to cause an abortion or miscarriage.²⁰

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.²¹ “Injuring a female partner in a way that may cause a miscarriage” is an example of “reproductive coercion.”²²

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.”²³ “The relationship between violence and

¹⁸ 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).

¹⁹ 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 15, at 2.

²⁰ Campbell et al., *supra* note 19, at 346.

²¹ C. McRann, *Man accused of beating girlfriend, causing abortion*, *Douglas Budget* (Feb. 22, 2012), <http://tinyurl.com/5n88d8xd>.

²² Chamberlain & Levenson, *supra* note 17, at 7.

²³ 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).

continuing or terminating a pregnancy is bidirectional” regarding coercion to continue a pregnancy or to end it.²⁴ 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.”²⁵

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.”²⁶

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

²⁴ Chamberlain & Levenson, *supra* note 17, at 14.

²⁵ *Id.*; ACOG 2013, *supra* note 16, at 1; Moore et al., *supra* note 18, 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).

²⁶ D. Callahan, *An ethical challenge to prochoice advocates*, 117 Commonweal 681, 684 (1990).

being pressured by their male partners to terminate pregnancies.”²⁷ They noted that no previous study had directly questioned women about coercion to abort and considered this a “potentially important reason for abortion.”²⁸

This study also revealed that pressure to abort “was extremely traumatic for some women and drove 1 woman to feel suicidal.”²⁹ 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 myself.”³⁰

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.

²⁷ Hathaway et al., *supra* note 25, 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.

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

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 textbooks (currently in use) list “perceived coercion” as a risk factor for having adverse psychological reactions after the abortion.³¹

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.³²

Another pertinent risk factor is a history of sexual, physical, or emotional abuse.³³ Thus, some women experiencing IPV may face increased mental health risks from abortion associated with multiple factors.

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

³¹ 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.

³² Baker 1999, *supra* note 31, at 29; Baker 2009, *supra* note 31, at 57.

³³ Baker 2009, *supra* note 31, at 57.

report stated that “feelings of commitment to the pregnancy predicted more negative postabortion responses.”³⁴

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.³⁵ 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.³⁶

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.³⁷

³⁴ American Psychological Association, *Report of the Task Force on Mental Health and Abortion* (2008), <https://perma.cc/6TR4-CD3L>, pp. 11, 92.

³⁵ *About Add Health*, <http://tinyurl.com/2ztbjrx3> (last visited Jan. 29, 2026).

³⁶ 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”).

³⁷ 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).³⁸

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.³⁹ 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 be a long-lasting source of disability, and a source of great distress.⁴⁰ A textbook

³⁸ Sullins 2019, *supra* note 36, at 1.

³⁹ P. Slade et al., *A comparison of medical and surgical termination of pregnancy*, 105 British J. of Obstetrics & Gynaecology 1288, 1288 (1998).

⁴⁰ American Psychiatric Association, *Diagnostic and statistical manual of mental disorders* (5th ed. 2013).

for abortion providers has also listed nightmares about babies as a potential adverse reaction to the abortion, though not specifically linked to chemical abortion.⁴¹ 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.⁴² “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.”⁴³

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

⁴¹ Baker 1999, *supra* note 31.

⁴² M. Hall et al., *Associations between intimate partner violence and termination of pregnancy*, 11 PLOS Medicine 1, 6 (2014).

⁴³ *Id.* (citing W.A. Fisher et al., *Characteristics of women undergoing repeat induced abortion*, 172 CMAJ 637, 640 (2005)).

researchers' findings support the concept that violence can lead to pregnancy and to subsequent termination of pregnancy, and that there may be a repetitive cycle of abuse and pregnancy.”⁴⁴

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.⁴⁵ 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.⁴⁶

Others with similar recommendations for such screenings include the nonprofit organization Futures Without Violence (formerly the Family Violence Prevention Fund)⁴⁷ and the National Academy of Medicine (which published guidelines in 2011 under its former name, the Institute of Medicine).⁴⁸

⁴⁴ Hall et al., *supra* note 42, at 25.

⁴⁵ ACOG 2013, *supra* note 16, at 1.

⁴⁶ ACOG 2012, *supra* note 15, at 3.

⁴⁷ Chamberlain & Levenson, *supra* note 17, at 3, 23, 37.

⁴⁸ *Id.* at 4.

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.”⁴⁹

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.

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.⁵⁰ “Women in the intervention group were more likely to report ending a relationship because the relationship was unhealthy or . . . felt unsafe.”⁵¹ 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.⁵² A practical suggestion is to “offer the patient immediate and private access to an

⁴⁹ *Id.*

⁵⁰ ACOG 2013, *supra* note 16, at 2.

⁵¹ *Id.*

⁵² ACOG 2012, *supra* note 15, at 4.

advocate in person or via phone.”⁵³ 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.⁵⁴

Education and discussion are considered essential even if the patient does not disclose abuse initially.⁵⁵ 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.”⁵⁶

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.”⁵⁷ If she were being abused, any of these people could be the abuser, so it is necessary to screen her alone.

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.”⁵⁸ The

⁵³ Chamberlain & Levenson, *supra* note 17, at 37.

⁵⁴ ACOG 2012, *supra* note 15, at 5.

⁵⁵ *Id.* at 3; ACOG 2013, *supra* note 16, at 3–4.

⁵⁶ Hall et al., *supra* note 42.

⁵⁷ ACOG 2012, *supra* note 15, at 3; ACOG 2013, *supra* note 16, at 3–4.

⁵⁸ National Abortion Federation, *Ethical Principles for Abortion Care* (2011), <https://perma.cc/EMC9-B7G7>.

National Abortion Federation states, “Providers have an ethical obligation to take reasonable precautions to keep their patients and staff safe.”⁵⁹

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.”⁶⁰ 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

⁵⁹ *Id.*

⁶⁰ 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).

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 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.⁶¹) 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

⁶¹ See American College of Obstetricians and Gynecologists, *Medication Abortion Up to 70 Days of Gestation*, <https://perma.cc/C25E-6K96>.

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."⁶²

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

⁶² I. Skop, *Chemical Abortion: Risks Posed by Changes in Supervision*, 27(2) J. of Am. Physicians and Surgeons 56, 58 (2022).

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.⁶³ 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.

⁶³ *Id.*

“The potential for misuse and coercion is high when there is no way to verify who is consuming the drug.”⁶⁴

There are cases in which men have obtained mifepristone and/or misoprostol and put them in a beverage without the knowledge of 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.⁶⁵

⁶⁴ *Id.*

⁶⁵ C. Robinson, *Man Gets 22 Years after Spiking Pregnant Girlfriend’s Drink with Abortion-inducing Drug*, Associated Press (Oct. 11, 2018).

Jeffrey Smith, another Wisconsin man, pled guilty to attempted first-degree intentional homicide of an unborn child.⁶⁶ 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.⁶⁷

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.⁶⁸ But as the weeks of gestation increase, so do the risks of serious adverse effects, including hospitalization or surgery.⁶⁹ 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

⁶⁶ 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>.

⁶⁷ 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.

⁶⁸ Mifeprex (mifepristone), package insert, Danco Labs (Sept. 28, 2000).

⁶⁹ I.M. Spitz, *Early pregnancy termination with mifepristone and misoprostol in the United States*, 338 N. Eng. J. Med. 1241, 1246 (1998).

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.⁷⁰

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.⁷¹ The current regulations provide more opportunities “for traffickers, domestic abusers, and men who do not want to become fathers to

⁷⁰ 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>.

⁷¹ L. Mungin, *Man pleads guilty to tricking pregnant girlfriend into taking abortion pill*, CNN (Sept. 10, 2013), <http://tinyurl.com/4wp79p32>.

surreptitiously give abortion pills to women,” since “these drugs can be so easily obtained by anyone.”⁷²

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.⁷³ 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,⁷⁴ 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

⁷² Skop, *supra* note 62, at 58.

⁷³ L. Lederer & C. Wetzel, *Health Consequences of Sex Trafficking*, 23 *Annals of Health Law* 61, 72–74 (2014).

⁷⁴ Janssen Neuroscience, Spravato, full prescribing information (2023), <http://tinyurl.com/73x5hzms>.

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.⁷⁵

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 pregnancies.⁷⁶ 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.⁷⁷ 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.⁷⁸

⁷⁵ Eli Lilly & Co., Zyprexa Relprevv, full prescribing information (2009), <http://tinyurl.com/3rsb76n4>.

⁷⁶ Danco Letter to ER Directors, pp. 1–2 (Nov. 12, 2004), <https://perma.cc/734R-LLSQ>.

⁷⁷ In such instances, the screening for an ectopic pregnancy would have failed.

⁷⁸ Danco Letter, *supra* note 76, at 2.

Ectopic pregnancy occurs in about 2% of all pregnancies.⁷⁹ Researchers at the Guttmacher Institute reported that there were 492,210 drug-induced abortions in 2020.⁸⁰ 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.⁸¹ There is no question that current practices will lead to grave harm for some women, and that many women are at risk from the many deficiencies of the current REMS—though the REMS have never provided adequate mitigation.

CONCLUSION

For these reasons, the Court should grant a stay against the 2023 REMS.

⁷⁹ American College of Obstetricians and Gynecologists, *Tubal Ectopic Pregnancy*, at e91, <https://perma.cc/HW5J-WSQF>.

⁸⁰ 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).

⁸¹ 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).

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/s Christopher Mills

Christopher Mills

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