Nos. 23-235, 23-236

In the Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,
Petitioners,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

DANCO LABORATORIES, LLC,
Petitioner,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

ON WRITS OF CERTIORARI TO THE UNITED STATES 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*

Amicus 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. We believe that all human life has been made in the likeness and image of God (Genesis 1:26). 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.*

Amicus 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 (IPV) 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 is a

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* Under Rule 37.6, no counsel for a party authored this brief in whole or in part, and no person other than *amici curiae*, their members, or their counsel made a monetary contribution to its preparation or submission.

graduate of Harvard Medical School's one-year Global Clinical Scholars Research Training Program. She has a certificate in Trauma and Recovery from Harvard and is a past participant of Notre Dame University's Vita Institute. 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. She has worked part-time for multiple pharmaceutical companies since 2010. 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.

The Family Research Council and Dr. Shuping believe that the Court should affirm the Fifth Circuit's order and remand for further proceedings.

SUMMARY OF THE ARGUMENT

Amici support the Fifth Circuit's decision to restore the FDA's previous protections for women's health and safety, before changes made by the FDA in 2016 and 2021. Because of the FDA's changes, it became possible for women to obtain abortion pills by mail without any in-person office visit with a medical professional—before, during or after the abortion. The only required contact under the relaxed regulations is an initial encounter with telemedicine, without any physical examination. The Fifth Circuit's decision to restore the former requirements is beneficial for several reasons.

First, doctors like the respondents' members are being exploited by FDA and the drug sponsors who have cobbled together an abortion platform that privatizes the up-side profits for those prescribing these pills while offering minimal patient care. Simultaneously, the mifepristone delivery apparatus off-loads or socializes mifepristone's risks and costs—monetary, emotional, and spiritual—to others like these physicians. Such "downstream doctors," are being injured by an abortion protocol in which their unwitting participation is a feature not a bug of making drug-induced abortion widely available to American society.

The respondents' members are not imagining this phenomenon. It is not speculative. As detailed below, about 20,000 women annually are expected to visit emergency rooms due to complications from mifepristone abortions. As mifepristone abortions garner greater market share, this number will likely increase. FDA's abortion delivery apparatus, as

amended in 2016 and 2021, could not function without their compelled assistance.

Second, we assess the purported benefits of the mifepristone regimen to women experiencing intimate partner violence (IPV). Some advocates for survivors of intimate partner violence support the concept of telemedicine for provision of abortion pills by mail in the mistaken belief that this is necessary for IPV survivors' health, well-being and safety.[1] But bypassing the substantial health benefits of an in-person visit with a physician places that woman at increased risk to her health, well-being and safety. Telemedicine abortions make it less likely that she will be able to escape that cycle of violence. Research and professional guidelines point to better options.

ARGUMENT

I. ER patient dumping is a feature, not a bug, of FDA's mifepristone regimen.

The 2016 and 2021 approvals have systematically reduced the required in-person patient contact for mifepristone patients. FDA's new telemed regime will leave many of the roughly one in 25 women seeking emergency room care without help.

The current mifepristone label states that 2.9–4.6% of women will require an emergency room visit.[2] This mirrors another established source. According to

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[1] See, *e.g.*, Brief of *Amici Curiae* Legal Voice, the National Domestic Violence Hotline, et al., in Support of Petitioners.

[2] Mifepristone Label, FDA-CDER, Table 2, rev. Jan. 2023, J.A. 533.

a health education page on the University of California San Francisco (UCSF) website, "[a]bout 3 to 5% of patients need an additional aspiration procedure due to ongoing pregnancy, prolonged or excessive bleeding, or preference."[3] So, roughly four percent or one in twenty-five mifepristone abortion patients will need to visit an E.R.

That turns out to be many, many women each year—roughly 20,000. Abortion researchers affiliated with the Guttmacher Institute have provided two key statistics. For 2020, there were 930,160 abortions, and 53% of them (492,210) were drug-induced.[4] Given the FDA and UCSF emergency room visit rates range from 2.9% (3%) to 4.6% (5%), a fair mid-range estimate would center on four percent. Four percent of 492,210 equals 19,688. And of course, procedure failure rates determined during research studies are probably lower than in real world circumstances in which patients don't follow protocol rules—and patient screening is of much lower quality. The same calculation using Guttmacher's 2017 data produces a similar but smaller total of 13,586, revealing the

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[3] UCSF Health, *Patient Education: Aspiration Versus Medication Abortion*, http://tinyurl.com/e7esj9tc (last visited Feb. 24, 2024), *cited in* A. Walker et al., *Are Abortion Pills Safe? Here's the Evidence*, New York Times (Apr. 1, 2023), http://tinyurl.com/t9v7bjpf. UCSF is deemed to be one of the top-ranked institutions conducting research on abortion including mifepristone abortions.

[4] 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).

increased preference for mifepristone abortions over the next three years.[5]

This staggering figure supports the claim of the respondent's physicians that they are not imagining some phenomenon that is impacting them professionally and ethically. These physicians' concerns are not speculative; they now appear to be a large-scale certainty. In fact, mifepristone patients presenting in emergency rooms is a feature not a bug of this protocol. Consequently, "downstream doctors," as we call them are an essential, if unwitting, part of the pharma abortion apparatus.

FDA stated in the 2000 approval documents that a critical part of care, in the event of a failed abortion, would be "access to . . . emergency services" which are "critical for the safe and effective use of the drug." J.A. 227. Reliance on emergency room treatment *always* had to be made an integral feature of the mifepristone regimen because FDA adamantly refused to require physicians performing mifepristone abortions to have admitting privileges at local hospitals where *they* could oversee the care of their patients.

Not surprisingly, four years after the regimen's approval, Danco felt the need to write a letter to all emergency room directors providing them with information from the mifepristone package insert.

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[5] For 2017, there were 862,320 abortions, and 39% of them (339,640) were drug-induced. Four percent of 339,640 equals 13,586. R.K Jones, E. Witwer, & J. Jerman, *Abortion Incidence and Service Availability the United States, 2017*, Guttmacher Institute (Sept. 2019), http://tinyurl.com/4abyrwaf.

Danco stated it was writing "to assist you in taking care of patients who may present in an emergency room following treatment with [the mifepristone regimen]." The letter went on to warn that "there may be some women who present to an emergency room with serious and sometimes fatal infections and bleeding."[6] The letter underscored the gravity of the situation: "A high index of suspicion is needed for timely diagnosis and intervention in these patients." Danco further emphasized that patients with ruptured ectopic pregnancies might also present.[7] Given these realities about the dangerousness of this drug-based abortion platform, it is all the more astonishing that in 2016 FDA altogether eliminated the requirement for participation by a licensed medical doctor. Now, after 2016, no participation by a licensed medical doctor is required at all.

Of course, telemed abortions exacerbate the problems of patient E.R. dumping. In the early 2000s, this may not have been a significant problem because fewer mifepristone abortions were being performed. But now, with half-a-million women per year using the mifepristone abortion regimen, the American medical community faces a serious problem.

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[6] Danco Letter to ER Directors (Nov. 12, 2004), p. 1, https://perma.cc/734R-LLSQ.
[7] *Id.* at 2.

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.

Intimate partner violence is a widespread public health problem that encompasses physical, psychological, and sexual violence by one's intimate partner or former partner.[8] "Approximately 324,000 pregnant women are abused each year in the United States."[9] "Approximately 1 in 4 women have been physically and/or sexually assaulted by a current or former partner."[10]

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[8] American College of Obstetrics and Gynecology, *Intimate Partner Violence*, Committee Opinion No. 518 (Feb. 2012, reaffirmed 2022), p. 1, http://tinyurl.com/mr3jvbew ("ACOG 2012").

[9] American College of Obstetrics and Gynecology, *Reproductive and Sexual Coercion*, Committee Opinion No. 556 (Feb. 2013, reaffirmed 2022), p. 2, http://tinyurl.com/yb5s7fsx ("ACOG 2013").

[10] 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://www.futureswithoutviolence.org/userfiles/file/HealthCare/Reproductive%20Health%20Guidelines.pdf.
This is a publication of American College of Obstetricians and Gynecologists jointly with Futures Without Violence.

There is increased risk of violence during pregnancy,[11] both as to frequency and severity.[12] In one study, interviews with women revealed that some of the men had admitted to beating the women to cause an abortion or miscarriage.[13]

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.[14] "Injuring a female partner in a way that may cause a miscarriage" is an example of "reproductive coercion."[15]

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

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[11] 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).

[12] 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 8 at 2.

[13] Campbell et al., *supra* note 12, at 346.

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

[15] Chamberlain & Levenson, *supra* note 10, at 7.

continue or terminate the pregnancy."[16] "The relationship between violence and continuing or terminating a pregnancy is bidirectional" regarding coercion to continue a pregnancy or to end it.[17] 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."[18]

In a U.S.-based study of IPV survivors experiencing reproductive coercion, some women reported pressure to continue the pregnancy, but the majority of women reported pressure to terminate the pregnancy. In a U.S. based study of IPV survivors experiencing reproductive coercion, some women reported pressure to continue their pregnancy while others who wanted their child reported "pressure and coercion to terminate a pregnancy."[19] For most of the women, the pressure was in the direction of ending the pregnancy. Some men threatened violence against these mothers to end the pregnancy, with one man reportedly stating, "If you don't get it done, I'm

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[16] 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).
[17] Chamberlain & Levenson, *supra* note 10, at 14.
[18] *Ibid.*; ACOG 2013, *supra* note 9, at 1; Moore et al., *supra* note 11, 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).
[19] Moore et al., *supra* note 11, at 1740–41.

throwing you down the steps, or I'm doing something!" Not every woman complied with the man's demands, but most did, with the result of 68% having abortions.

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."[20]

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."[21] They noted that no previous study had

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

[21] Hathaway et al., *supra* note 18, 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

directly questioned women about coercion to abort and considered this as a "potentially important reason for abortion."[22]

This study also revealed that pressure to abort "was extremely traumatic for some women and drove 1 woman to feel suicidal."[23] 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.'"[24]

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

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the topic of coerced abortion to be important. This study was also cited by Chamberlain & Levenson (2012), in a report jointly published by ACOG and Futures Without Violence, highlighting its importance.

[22] *Ibid.*

[23] *Ibid.*

[24] *Ibid.*

coercion" as a risk factor for having adverse psychological reactions after the abortion.[25]

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 women 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 women'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.[26]

Another pertinent risk factor is a history of sexual, physical, or emotional abuse.[27] Thus, some women experiencing IPV may face increased mental health risks from abortion associated with multiple factors.

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[25] 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.

[26] Baker 1999, *supra* note 25, at 29; Baker 2009, *supra* note 25, at 57.

[27] Baker 2009, *supra* note 25, 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."[28]

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.[29] 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.[30]

This high-quality dataset has become a resource for more than 30,000 researchers and has led to more

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[28] American Psychological Association, *Report of the Task Force on Mental Health and Abortion* (2008), http://www.apa.org/pi/wpo/mental-health-abortion-report.pdf, pp. 11, 92.

[29] *About Add Health*, http://tinyurl.com/2ztbjrx3 (last visited Feb. 27, 2024).

[30] 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").

than 8,000 publications.[31] 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.[32]

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).[33]

Thus, women who are coerced by an abuser to abort a wanted child are likely to experience a significant

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[31] Add Health, *Publications*, http://tinyurl.com/2rc7jynm (last visited Feb. 27, 2024).

[32] D.P. Sullins, *Abortion, substance abuse and mental health in early adulthood*, Sage Open Medicine, p. 2, http://tinyurl.com/4z3pptfc (2016).

[33] Sullins 2019, *supra* note 30, at 1.

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."[34]

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.[35] 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 posttraumatic stress disorder (PTSD), a disorder that can be a long-lasting source of disability, and a source of great distress.[36] A textbook for abortion providers has also listed nightmares about babies as a potential adverse reaction to the abortion, though not

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[34] *Id.* at 14.

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

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

specifically linked to chemical abortion.[37] 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.[38] "The highest quality study found that women presenting for a third TOP [termination of pregnancy] were over two and half times more likely to have a history of physical or sexual violence than women presenting for their first."[39]

In a study of 1,318 Boston-area males that was included in the meta-analysis, perpetrators of IPV

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[37] Baker 1999, *supra* note 25.
[38] M. Hall et al., *Associations between intimate partner violence and termination of pregnancy*, 11 PLOS Medicine 1, 6 (2014).
[39] *Ibid.* (citing W.A. Fisher et al., *Characteristics of women undergoing repeat induced abortion*, 172 CMAJ 637, 640 (2005)).

were more likely to have been involved in three *or more* pregnancies ending in abortion.[40]

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 subsequent termination of pregnancy, and that there may be a repetitive cycle of abuse and pregnancy."[41]

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

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

The American College of Obstetrics and Gynecology (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.[42] 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.[43]

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[40] Silverman et al., *supra* note 16, at 1416.
[41] Hall et al., *supra* note 38, at 25.
[42] ACOG 2013, *supra* note 9, at 1.
[43] ACOG 2012, *supra* note 8, at 3.

Others with similar recommendations for such screenings include the nonprofit organization Futures without Violence,[44] Family Violence Prevention Fund,[45] and the National Academy of Medicine (which published guidelines in 2011 under its former name, the Institute of Medicine, IOM).[46]

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."[47]

It should be clear to anyone who is engaged in the practice of medicine that screening and counseling for IPV is not optional but should be a routine part of the provision of health care, and 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.[48] "Women in the intervention group were more likely to report ending

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[44] Chamberlain & Levenson, *supra* note 10, at 4.
[45] *Id.* at 37.
[46] *Id.* at 4.
[47] *Ibid.*
[48] ACOG 2013, *supra* note 9, at 2.

a relationship because the relationship was unhealthy or . . . felt unsafe."[49] 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.[50] A practical suggestion is to "offer the patient immediate and private access to an advocate in person or on the phone."[51] 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.[52]

Education and discussion are considered essential even if the patient does not disclose abuse initially.[53] 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."[54]

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[49] *Ibid.*
[50] ACOG 2012, *supra* note 8, at 4.
[51] Chamberlain & Levenson, *supra* note 10, at 37.
[52] ACOG 2012, *supra* note 8, at 5.
[53] *Id.* at 3; ACOG 2013, *supra* note 9, at 3–4.
[54] Hall et al., *supra* note 38.

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."[55] 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."[56] The National Abortion Federation also states, "Providers have an ethical obligation to take reasonable precautions to keep their patients and staff safe."[57]

D. Video visits are not reliably confidential.

During video visits (when tablets 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.

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[55] ACOG 2012, *supra* note 8, at 3; ACOG 2013, *supra* note 9, at 3–4.
[56] National Abortion Federation, *Ethical Principles for Abortion Care* (2011), http://tinyurl.com/msfjp7zv.
[57] *Ibid.*

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."[58] But when video 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 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. Likewise, since the National Abortion Federation states the necessity of

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[58] 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).

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, since an abusive partner may be enforcing his decision that she abort, the abortion is not at all likely to serve as a means to escape trauma and violence, but the experience that perpetuates a cycle of repeated violence. Women who have been living with violence at home often are 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."[59]

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[59] 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.[60] 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 removed an important safeguard for preventing diversion of abortion pills to those who may intend harm to others.

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[60] *Ibid.*

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 potential for misuse and coercion is high when there is no way to verify who is consuming the drug."[61]

There are cases in which men have obtained mifepristone and/or misoprostol and put it 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

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[61] *Ibid.*

attempted first-degree intentional homicide of an unborn child after he slipped mifepristone, obtained from India by mail, into his girlfriend's drink.[62]

Jeffrey Smith, another Wisconsin man, pled guilty to attempted first-degree intentional homicide of an unborn child.[63] 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.[64]

Mifepristone was originally approved in the U.S. for use only up to 49 days gestation, though it is now permitted by the FDA up to 10 weeks.[65] But as the weeks of gestation increase, so do the risks of serious adverse effects and needing hospitalization or surgery.[66] In this case, the woman did not

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

[63] 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.

[64] 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 regime at Smith's home; only the first drug in the regimen, mifepristone, had been used to poison his girlfriend and her baby.

[65] Mifeprex (mifepristone), package insert, Danco Labs (Sept. 28, 2000).

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

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 20 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 this 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.[67]

This example illustrates that men try to abort their unborn children, without knowledge of or interest in the safety of the mother, nor 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

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[67] 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.

he used predated the current pills-by-mail system now available.[68] The current regulations provide even more opportunities "for traffickers, 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."[69]

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 at least some of them were forced.[70] 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/or reducing the risk of diversion that would lead to harm to others. These include narcotic pain medications, which have potential risks to patients and also to others if diverted to others as considered above.

Another medication with dual risks, both safety and risk of diversion, is the psychiatric medication,

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

[69] Skop, *supra* note 59, at 58.

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

Spravato,[71] 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.

Two other psychiatric medications also are under a REMS: Clozapine, due to the necessity of frequent blood monitoring for safety,[72] and Zyprexa Relprev, which requires administration at a healthcare facility with a three-hour period of monitoring afterward, for safety reasons.[73]

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. As discussed above, Danco's November 12, 2004 letter to emergency room directors raised a number of serious safety concerns, including about infection, sepsis, hemorrhage, and ectopic pregnancies.[74] Although we have not discussed it, the possibility of an ectopic pregnancy continuing to develop after the patient has begun the mifepristone regimen should be

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[71] Janssen Neuroscience, Spravato, full prescribing information (2023), http://tinyurl.com/73x5hzms.
[72] Novartis Pharmaceutical Co., Clozaril, full prescribing information, http://tinyurl.com/2a8s7afy.
[73] Eli Lilly & Co., Zyprexa Relprev, full prescribing information (2009), http://tinyurl.com/3rsb76n4.
[74] Danco Letter, *supra* note 6, at 1–2.

a matter of significant concern.[75] 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.[76]

Ectopic pregnancy occurs in 1-2% of all pregnancies.[77] As noted above, researchers at the Guttmacher Institute reported that there were 492,210 drug-induced abortions in 2020.[78] 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 more accurate figure, then 9,844 women in this group would be at risk for this life-threatening problem annually.

It is clear from Danco's letter and over twenty years of experience that mifepristone is *not* a low-risk medication.[79] 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

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[75] In such instances, the screening for an ectopic pregnancy would have failed.

[76] Danco Letter, *supra* note 6, at 2.

[77] E. Hendricks et al., *Ectopic Pregnancy: Diagnosis and Management*, 101 Am. Fam. Physician 599 (2020).

[78] R.K Jones et al., *supra* note 4, at 128.

[79] 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).

of the current REMS—though the REMS have never provided adequate mitigation.

CONCLUSION

Mifepristone is a drug like no other. A woman can conveniently take it in the privacy of her own home, expecting to end her pregnancy with little difficulty, then find herself alone and without physical or emotional support as she views in horror her unborn child in the toilet or in her hand. At the same time, she is likely to be experiencing intense pain, severe cramping, bleeding, with nausea and/or vomiting—side effects that have been demonstrated to be more severe with mifepristone abortions than surgical abortions.[80]

Along with the long-lasting psychological and spiritual distress that can arise from this experience, there are serious, even life-threatening, adverse effects that have occurred. In some cases, women have died. In fact, FDA acknowledges that about one in twenty-five mifepristone abortion patients will require an emergency room visit for various reasons. Few, if any, other legal drugs exist that can cause patients using it as prescribed to visit an emergency room at this rate.

One might have expected that such a drug would be administered under tight supervision and with an ironclad protocol designed to get patients help when emergencies arose. That is not how FDA has regulated mifepristone. *Amici* felt strongly at the time that the

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[80] N. Dworkin-McDaniel, *I was betrayed by a pill*, Marie Claire (June 27, 2007), http://tinyurl.com/2s3848c9.

2000 approval's restrictions were weak and inadequate. And FDA has spent the last two decades hollowing out even those insufficient safety provisions. In 2016 and 2021 FDA issued a set of Potemkin REMS. These protocols have allowed abortion providers to inch ever closer to do-it-yourself drug-induced abortions, which seems to be FDA's ultimate objective.

From 2000, FDA knew that dumping emergency patients onto unsuspecting physicians and healthcare workers was a critical element in making the system work. The respondent's members here are "downstream doctors" whose exploitation has been predictable and palpable. Their careers are being jeopardized by healthcare providers who have privatized the up-side profits of prescribing these pills while offering minimal actual patient care. Simultaneously, these providers have socialized mifepristone's risks and costs whether monetary, emotional, or spiritual to others.

A drug regimen like this is not rational, and its creation has not been supported by science. In fact, this regimen defies the basic tenets of good patient care based on a century of medical learning.

Women experiencing IPV are at risk for coerced abortions of *wanted* children, which is associated with high risk of depression and suicidal ideation. Abortion is not a solution to IPV but only perpetuates a cycle of violence. The best help for women is to have, before the procedure, a genuine screening for IPV and coercion along with education and provision of resources, as recommended by many authorities. Being screened privately for possible coercion will give

assurance that she has the pregnancy outcome she truly desires, including giving birth to a wanted baby. And being informed about resources and receiving help to access them will change the lives of IPV survivors for the better. It will lead to improved health, well-being, and safety.

Women are not helped by cutting corners and being abandoned to manage their abortions alone. Any woman considering abortion deserves a real doctor-patient relationship, with an evaluation at the start, to fully assess the facts of her case and life, some of which would not be known without a physical exam at the start. The FDA's decision to remove protections in 2016 and 2021 endangers women's health and safety. Restoration of these protections best serves the needs of women's health and safety, including women experiencing IPV. To restore safeguards that FDA removed, the Court should affirm.

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