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, L.L.C.,
Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

On Writs of Certiorari to the United States Court of Appeals for the Fifth Circuit

AMICI BRIEF OF THE ELLIOT INSTITUTE, RACHEL'S VINEYARD, & ENTERING CANAAN MINISTRY IN SUPPORT OF RESPONDENTS

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The Elliot Institute is an organization dedicated to research and education regarding the physical and psychological effects of abortion on women. Rachel's Vineyard and Entering Canaan Ministry, Inc. are non-profit organizations providing post-abortion healing programs for women and men who suffer psychosocial and physical complications from induced abortions.

This amici brief addresses the fact that the vast majority of abortions are *contraindicated* due to the presence of risk factors that foreseeably identify women at the highest risk of suffering negative effects of induced abortion without any direct benefits. Amici advocate for the interests of millions of women injured by abortions, especially unwanted and poorly regulated abortions, for which the proven risks clearly outweigh any theoretical and unproven benefits.

SUMMARY OF ARGUMENT

The FDA and its amici present the agency's approval of mifepristone, and subsequent loosening of the REMS, as examples of bureaucratic expertise at its finest. That depiction could hardly be farther from the truth. The FDA's review and approval of mifepristone was arbitrary, capricious, and even the result of willful malfeasance. The FDA has failed to protect women's health and well-being, especially

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[1] No counsel for any party authored this brief in whole or in part. No such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity aside from amici, their members, or their counsel made a monetary contribution to the preparation or submission of this brief.

among the subset of women at greatest risk of injuries from abortion. This malfeasance was due to a wrongful prioritization of political goals and social engineering objectives.

The FDA breached its normal protocols for drug approval by never requiring double-blind trials proving that abortion by mifepristone, or of any type, directly contributes to the physical or psychosocial health of women. The only test of efficacy the FDA required was that most mifepristone-induced abortions were completed—i.e., the medication triggered a miscarriage—without additional surgical intervention.

A completed abortion is not in and of itself beneficial. Most women seeking abortions are looking for specific psychosocial benefits. Yet, none of these hoped-for benefits have been proven to result from abortion.

Conversely, there is undeniable and overwhelming evidence that abortion contributes to physical and psychosocial harm, especially to those women who consent to abortions contrary to their own values and preferences due only to pressures they face from other people or from circumstances. These women constitute a majority of women who obtain abortions. Therefore, at best, a minority of women claim no collateral harm from induced abortions.

Yet, the FDA has done nothing to limit the prescription of mifepristone to this small minority. Instead, its actions have predictably contributed to avoidable injuries of millions of women.

Because of political motivations, the FDA has failed to adhere to its normal standards for determining that a reasonable, evidence-based risk versus benefits assessment has demonstrated when,

if ever, the proven benefits of mifepristone induced abortions outweigh their associated risks.

The best evidence indicates that the risks of abortion are greater than proven benefits, if any, especially for the majority of women who feel pressured to abort contrary to their own values and preferences. The FDA's approval of mifepristone and expansion of its availability are therefore unjustified.

ARGUMENT

I. ABORTION PILLS ADVANCE HISTORICAL EUGENIC AND POPULATION CONTROL GOALS, NOT THE INDIVIDUAL WELL-BEING OF WOMEN.

The claim that abortion benefits the personal autonomy of women is nothing more than an abstract ideal. In practice, easier access to abortion has simply made it easier to pressure women into unwanted abortions.

According to one study, 64% of women report having been pressured into abortions by others.[2] Another study found that those who feel pressured (over 60% of women) are more likely to state that their abortions directly contributed to a decline in mental health, disruptions of work and relationships, and intrusive thoughts about their abortions.[3] Even pro-abortion researchers report that only a minority of women (42%) seeking abortions described their

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[2] Vincent M. Rue et al., *Induced Abortion and Traumatic Stress: A Preliminary Comparison of American and Russian Women*, 10 Med. Sci. Monitor SR5, SR9 (2004).

[3] David C. Reardon & Tessa Longbons, *Effects of Pressure to Abort on Women's Emotional Responses and Mental Health*, Cureus, Jan. 31, 2023, at 8 [hereinafter *Effects of Pressure to Abort*].

pregnancies as unwanted.[4] Most aborting women reported that they would have welcomed giving birth with changed circumstances, such as "more support from others," "emotional support," or "more financial security."[5] In addition, 67% report that their abortion decisions violated their own values and preferences, were unwanted, or were coerced.[6]

The fact that easier access to abortion would increase the number of unwanted and unsafe abortions was not unexpected. The movement to legalize abortion in the United States was initiated and driven by eugenicists and population controllers, not feminists.[7] Though these social engineers were quick to pretend that abortion was a boon to womankind, their true goal was always to increase abortion rates for social engineering purposes, regardless of the effects on individual women.

For example, Lawrence Lader, co-founder of the National Association for the Repeal of Abortion Laws (NARAL), claimed credit for convincing Betty Friedan and her National Organization of Women to embrace "a woman's right to control her own body" while actively pursuing his own population control efforts.[8]

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[4] *See* M. Antonia Biggs et al., *Developing and Validating the Psychosocial Burden Among People Seeking Abortion Scale (PB-SAS)*, PLOS One, Dec. 10, 2020, at 6.

[5] David C. Reardon et al., *The Effects of Abortion Decision Rightness and Decision Type on Women's Satisfaction and Mental Health*, Cureus, May 11, 2023, at 4 [hereinafter *Effects of Abortion Decision Rightness*].

[6] *Id*.

[7] Rebecca Messall, *The Long Road of Eugenics: From Rockefeller to* Roe v. Wade, Hum. Life Rev., Fall 2004, at 2.

[8] Lawrence Lader, *Abortion II: Making the Revolution* 36 (1973); Bernard N. Nathanson & Richard N. Ostling, *Aborting America* 32, 49-53 (1st ed. 1979).

Lader was a board member of Zero Population Growth, Inc., author of *Breeding Ourselves to Death*, and a biographer of Planned Parenthood's Margaret Sanger. According to Lader: "In a larger sense, each woman who decides whether or not a fetus should become a child affects the population charts."[9] Therefore, he argued, increasing abortion rates was essential to reduce the social burden of the "unwanted classes" and the related risk of "the violent rebellion of minority groups."[10]

Similar motives were revealed in what became a world-changing letter from Ron Weddington, now archived in the William J. Clinton Presidential Library.[11] Weddington had been co-counsel in *Roe v. Wade* with his wife Sarah.[12] Weddington argued that there was an urgent need to "eliminate the barely educated, unhealthy and poor segment of our country."[13] In the accompanying cover letter directed to Clinton's Director for Public Outreach, Weddington wrote, "26 million food stamp recipients is more than the economy can stand."[14]

The key to Weddington's plan was to license Roussel Uclaf's new abortion pill to a non-profit group, to "eliminate the need for product liability

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[9] Lader, *supra* note 8, at 2.

[10] *Id*. at 156-57.

[11] Letter from James R. Weddington to President-To-Be-Clinton, Presidential Candidate (Jan. 6, 1992) (on file with the William J. Clinton Presidential Library), http://tinyurl.com/53jswkyb.

[12] *Id.*; *Sarah Weddington: Lawyer & Reproductive Rights Activist*, Life Stories, http://tinyurl.com/2mvv3jyt (last visited Feb. 16, 2024).

[13] Letter from James R. Weddington to President-To-Be-Clinton, *supra* note 11.

[14] Letter from James R. Weddington to Betsey Wright, Director for Public Outreach, Clinton Transition Team (Jan. 6, 1992) (on file with the William J. Clinton Presidential Library), http://tinyurl.com/53jswkyb.

insurance."[15] Clinton encouraged negotiations between Roussel Uclaf and the non-profit Population Council to promote the testing and licensing of RU-486 in the United States.[16]

Ultimately, the RU-486 patent rights were given to the Population Council,[17] notably founded by eugenicists John D. Rockefeller III and Frederick Osborn, the latter of whom was also "a founding member of the American Eugenics Society."[18] After the word "eugenics" had fallen into disfavor following WWII, the pair founded the Population Council to advance and rebrand eugenic objectives within the lexicon of population control and to blaze the way toward repealing laws restricting abortion.[19] The goal of reducing birthrates of the poor, here and abroad, remained the same.[20]

In short, the Clinton Administration's work to bring mifepristone to market as speedily as possible was not driven by evidence of any direct benefits to women's health. It was driven by political and social

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[15] Letter from James R. Weddington to Betsey Wright, *supra* note 14; Letter from Bill Clinton to Edouard Sakiz, Chairman of the Supervisory Board, Roussel Uclaf (May 16, 1994) (on file with the William J. Clinton Presidential Library), http://tinyurl.com/53jswkyb.

[16] *Id*.

[17] Press Release, Dep't of Health & Hum. Servs., Statement of Donna E. Shalala, Sec'y of Health & Hum. Servs. (May 16, 1994) (on file with the William J. Clinton Presidential Library), http://tinyurl.com/53jswkyb.

[18] *Rockefeller III Births the Population Council*, Philanthropy Roundtable, https://www.philanthropyroundtable.org/almanac/rockefeller-iii-births-the-population-council/ (last visited Feb. 16, 2024); Messall, *supra* note 7, at 11-12.

[19] *See generally* Messall, *supra* note 7.

[20] *Id*.

engineering goals—and a reckless disregard for women's health.

II. INDUCED ABORTIONS, INCLUDING MIFEPRISTONE, HAVE NOT BEEN SHOWN DIRECTLY TO BENEFIT THE PHYSICAL OR PSYCHOSOCIAL HEALTH OF WOMEN.

Most abortions are sought for psychosocial reasons. For example, some women seek abortions hoping to save relationships with men threatening to leave them if they do not abort. Yet, there is no evidence when, if ever, this goal is achieved.

Other women are told that having an abortion will protect them from poverty, depression, a failed career, or some familial or social shame. Yet there is no evidence of when, if ever, any of these goals are achieved.

More importantly, from a regulatory perspective, there is no evidence of when, if ever, abortion is the *direct cause* (not an incidental event) of obtaining any measurable benefits.

That is what double-blind placebo-controlled drug trials are intended to prove: that the drug is the direct cause of some measurable benefit in physical or psychosocial health. Absent such evidence, there is no proof of efficacy.

Contrary to the law and its own regulations regarding every other drug, the FDA approved mifepristone without any statistically validated evidence of physical or psychosocial benefits directly attributable to mifepristone-induced abortions. In this unique case, their sole criteria for declaring mifepristone was efficacious was that a high percentage of mifepristone-induced abortions were

completed without the need for surgical intervention.[21]

That was not a proper measure of efficacy in addressing the actual problem. That was a measure of abortion completion rates.

While a high rate of completed abortions is of prime importance to population controllers, it is not evidence that all patients, or even most, experienced any hoped-for physical or psychosocial benefits directly attributable to their abortions.

III. THE FDA HAS IGNORED ALL PSYCHOSOCIAL HARMS AND MOST PHYSICAL HARMS ASSOCIATED WITH ABORTION.

Normally, the standard of proof for demonstrating a drug's efficacy (benefits) requires proof of a causal connection.[22] This is why double-blind trials are required to prove that the benefits are greater than non-treatment or placebos.[23] As noted, that standard has never applied to the FDA's mifepristone review process.[24]

A different standard applies to adverse effects. The FDA's own rules exclude the necessity of proving a

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[21] *See generally* David C. Reardon et al., *Overlooked Dangers of Mifepristone, the FDA's Reduced REMS, and Self-Managed Abortion Policies: Unwanted Abortions, Unnecessary Abortions, Unsafe Abortions* 10 (2021) [hereinafter *Overlooked Dangers*].

[22] *See* Demonstrating Substantial Evidence of Effectiveness Based on One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence; Draft Guidance for Industry; Availability, 88 Fed. Reg. 64,445, 64,446 (Sept. 19, 2023), http://tinyurl.com/42er7y4h.

[23] Sara Ryding, *What is a Double-Blind Trial?*, News Medical, https://www.news-medical.net/health/What-is-a-Double-Blind-Trial.aspx (Mar. 19, 2021).

[24] *Overlooked Dangers*, *supra* note 21, at 14-16.

causal relationship between adverse effects and the drug.[25] Merely "reasonable evidence of an association" requires a warning of the associated risk.[26]

It is upon this basis that the Eighth Circuit rejected Planned Parenthood's claim that an absence of definitive proof that abortion in and of itself was the direct and sole cause of subsequent suicides, their patients should not be told of the many studies showing a strong statistically significant elevated rate of suicide in the months immediately following exposure to abortion.[27]

With every other drug, "reasonable evidence of an association" between a risk and a treatment is sufficient to at least warrant a warning,[28] much less a contraindication of use. But, for mifepristone, this standard of weighing and disclosing risks has not been applied either to the approval process or to subsequent reviews and regulations.

Specifically, the FDA's original REMS mandated only the reporting of "serious" physical complications requiring surgical intervention.[29] Even worse, that substandard requirement relied mostly on non-systematic, voluntary reporting of "known" complications.[30]

Most egregiously, the FDA has never required any systematic follow-up of any psychosocial problems associated with mifepristone-induced abortions, or any physical complications beyond the first week, nor

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[25] 21 C.F.R. § 201.80(e).
[26] *Id.*
[27] *See Planned Parenthood Minn., N.D., S.D. v. Rounds*, 686 F.3d 889, 895-98 (8th Cir. 2012) (en banc).
[28] 21 C.F.R. § 201.80(e).
[29] *Overlooked Dangers*, *supra* note 21, at 8-9.
[30] *Id.*

even a systematic search for death certificates associated with the study population.[31]

Moreover, the FDA has ignored all peer-reviewed studies demonstrating statistically significant risks associated with abortion. Notably, while some of the following examples are specific to mifepristone-induced abortions, studies regarding risks associated with abortion of any type should also be assumed as applicable to medical abortions unless there is clear and compelling evidence that the associated risks are only associated with surgical abortions.

A. Abortion Is Indisputably Linked to Elevated Risk of Negative Mental Health Effects

The best data on American women is found in a 2016 study using the National Longitudinal Study of Adolescent to Adult Health ("Add Health") that provided three models of analyses, including controls for over twenty covariates and other confounding factors.[32] In addition, the author conducted a fixed-effects regression analysis controlling for within-person variations to control "for all unobserved or unmeasured variance that may covary with abortion and/or mental health."[33] These lagged models, employed as additional means of examining effects of prior mental illness, confirmed that the risks associated with abortion cannot be fully explained by prior mental disorders.

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[31] *Id*.

[32] Donald Paul Sullins, *Abortion, Substance Abuse and Mental Health in Early Adulthood: Thirteen-Year Longitudinal Evidence from the United States*, SAGE Open Med., Sept. 2016, at 6.

[33] *Id*. at 8.

This study also identified a dose effect, with *each exposure to abortion* (up to four) associated with a 23% increase in relative risk of subsequent mental disorders.[34] In addition, a subsequent 2019 analysis using the same data set revealed that over 18% of the women having abortions reported wanting the child.[35] Unsurprisingly, the women who aborted wanted children experienced a 122% higher rate of depression and a 244% higher rate of suicidality.[36]

Notably, this federally funded Add Health longitudinal data is publicly available. It has been examined by abortion proponents, yet no refutation of the above findings has ever been raised. These important findings remain undisputed. They are simply ignored.

A comprehensive review of the literature also reveals that there is no dispute that negative emotions are common after abortion and that abortion *contributes* to mental illness.[37] The only dispute is over when, if ever, abortion is the *direct and sole cause* of mental illness.[38] While it is known that women with pre-existing mental health problems, on average, require an increase in mental health treatments

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[34] *Id*.

[35] Donald P. Sullins, *Affective and Substance Abuse Disorders Following Abortion by Pregnancy Intention in the United States: A Longitudinal Cohort Study*, Medicina, Nov. 15, 2019, at 2.

[36] *Id.* at 10.

[37] David C. Reardon, *The Abortion and Mental Health Controversy: A Comprehensive Literature Review of Common Ground Agreements, Disagreements, Actionable Recommendations, and Research Opportunities*, SAGE Open Med., Oct. 29, 2018, at 13 [hereinafter *Abortion and Mental Health Controversy*].

[38] Brenda Major et al., *Report of the APA Task Force on Mental Health and Abortion* 16 (2008).

following an abortion,[39] and that those *without* preexisting mental health issues also experience more mental health problems compared to similar women after an abortion,[40] abortion proponents still insist that there is insufficient evidence to prove that abortion is the *sole and direct cause* of the decline in mental health consistently observed in representative samples of women who have had abortions.

In short, abortion providers are arguing that even though a majority of women with a history of abortion blame it directly as a cause for the decline in their mental health,[41] the best explanation for this phenomenon is to blame their victims: women who abort are simply more likely to be mentally flawed prior to their abortions.[42]

However, pre-existing mental illness is just one of the fifteen risk factors explaining the higher rates of mental illness consistently observed after abortion and identified by the American Psychological Association's Task Force on Mental Health and Abortion ("TFMHA") in 2008.[43] Among the other risk factors identified by TFMHA are "perceived pressure from others to terminate a pregnancy," "ambivalence about the abortion," and "a history of prior

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[39] James Studnicki et al., *A Cohort Study of Mental Health Services Utilization Following a First Pregnancy Abortion or Birth*, 15 Int'l J. Womens Health 955, 958 (2023).

[40] *Id.*; David C. Reardon & Christopher Craver, *Effects of Pregnancy Loss on Subsequent Postpartum Mental Health: A Prospective Longitudinal Cohort Study*, Int'l J. Env't Rsch. & Pub. Health, Feb. 23, 2021, at 1.

[41] *Effects of Pressure to Abort*, *supra* note 3, at 8; *Effects of Abortion Decision Rightness*, *supra* note 5, at 7.

[42] *Abortion and Mental Health Controversy*, *supra* note 37, at 6; Sullins, *supra* note 32, at 2; Major et al., *supra* note 38, at 4.

[43] *Abortion and Mental Health Controversy*, *supra* note 37, at 3; Major et al., *supra* note 38, at 11.

abortion."[44] These risk factors alone, much less in combination with the other twelve risk factors not identified here, appear among the vast majority (over 70%) of women seeking abortions.[45]

Screening for such risk factors, especially coercion, should be the duty of every abortion provider.[46] But this duty is typically ignored. The FDA's decision to allow mail-order abortion kits only serves to exacerbate the problem of inadequate pre-abortion screening.

Regarding the differences in the psychological effects associated with medical versus surgical abortions, the literature is surprisingly limited. One of the few randomized trials conducted found that two weeks after the abortion, medical abortion was linked to *higher* scores on emotional distress scales than surgical abortion.[47] The women provided with medical abortions also reported more pain and bleeding and less willingness to consider a medical abortion in the future.[48]

Another study surveying volunteers both a few hours and six weeks after their abortions found that 38% of the women had symptoms of post-traumatic stress disorder (PTSD) and that the risk was

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[44] *Abortion and Mental Health Controversy*, *supra* note 37, at 3.
[45] *Abortion and Mental Health Controversy*, *supra* note 37, at 3; *Effects of Pressure to Abort*, *supra* note 3, at 1.
[46] David C. Reardon, *Abortion Decisions and the Duty to Screen: Clinical, Ethical, and Legal Implications of Predictive Risk Factors of Post-Abortion Maladjustment.*, 20 J. Contemp. Health Law Policy 33 (2003).
[47] T. Kelly et al., *Comparing Medical Versus Surgical Termination of Pregnancy at 13-20 Weeks of Gestation: A Randomised Controlled Trial*, 117 BJOG 1512, 1514-15 (2010).
[48] *Id*. at 1516.

significantly greater after a medical abortion compared to a surgical abortion.[49]

These findings are consistent with the theory that medical abortions are more psychologically stressful because (a) women are more likely to see blood and human remains, (b) by taking the medication directly, women cannot shift blame for the abortion to the surgeon who "did it" to them, and (c) the abortion process is much more prolonged.

In addition, elevated rates of symptoms associated with depression and anxiety observed in animal experiments with mifepristone-induced abortions[50] suggest that there may be a biological component contributing to the increased rates of psychological problems observed after abortion.[51]

B. Abortion Is Indisputably Linked to Elevated Risk of Negative Physical Effects, Including Elevated Mortality

Abortion advocates frequently claim that CDC statistics demonstrate that mortality rates following abortion are lower than those following childbirth.[52] Since there is no systematic reporting or investigation

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[49] C. Rousset et al., *Posttraumatic Stress Disorder and Psychological Distress Following Medical and Surgical Abortion*, 29 J. Reprod. & Infant Psych. 506, 512 (2011).

[50] Christina Camilleri et al., *Biological, Behavioral and Physiological Consequences of Drug-Induced Pregnancy Termination at First-Trimester Human Equivalent in an Animal Model*, Frontiers Neurosci., May 29, 2019, at 3.

[51] *See Abortion and Mental Health Controversy*, *supra* note 37; Sullins, *supra* note 32.

[52] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstet. & Gynecol. 215, 215 (2012).

of abortion associated deaths,[53] however, the two numbers they compare for maternal death rates and reported abortion deaths are not comparable, as even the CDC has noted.[54]

In fact, every time deaths associated with birth and abortion are measured using the same objective standard (by linking all death certificates to complete reproductive health records), it has been proven that the mortality rate after abortion is significantly higher than that of carrying pregnancies to term.[55]

Deaths by suicide, accidents (which may reflect elevated risk-taking and suicidal behaviors), and cardiovascular disease are the causes of death most raised following abortion.[56] There is even a dose effect, with each abortion contributing to a 50% increased risk of premature death. Remarkably, the only systematic evidence-based investigation of maternal deaths which sought to identify which, if any deaths, might have been avoided by access to abortion concluded that none of the investigated deaths could have been avoided.[57]

In short, contrary to the disinformation from abortion proponents, abortion is not safer than childbirth. Instead, abortion is clearly associated with

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[53] David C. Reardon et al., *Deaths Associated with Abortion Compared to Childbirth—A Review of New and Old Data and the Medical and Legal Implications*, 20 J. Contemp. Health L. & Pol'y 279, 309 (2004).

[54] David C. Reardon, *Rebuttal of Raymond and Grimes*, 79 Linacre Q. 259, 259 (2012).

[55] David C. Reardon & John M. Thorp, *Pregnancy Associated Death in Record Linkage Studies Relative to Delivery, Termination of Pregnancy, and Natural Losses: A Systematic Review with a Narrative Synthesis and Meta-Analysis*, SAGE Open Med., Nov. 2017, at 20.

[56] *Id*.

[57] J. F. Murphy & K. O'Driscoll, *Therapeutic Abortion: The Medical Argument.*, 75 Ir. Med. J. 304, 306 (1982).

an elevated risk of premature death. Moreover, there is no clear and convincing evidence that abortion can ever prevent a maternal death. In most cases of maternal disease or injury, inducing a premature delivery would be a safer and more effective option.[58]

There are also other physical health risks. Numerous studies have shown an association between abortion and elevated risk of subsequent cardiovascular diseases.[59] The link between abortion and breast cancer has been strengthened by a recent Chinese study, which found that women with two or more abortions had seven times the rate of breast cancer, making it even a more important risk factor than family history or body mass index.[60]

These citations touch just the surface of a large body of literature linking abortion to elevated risk of physical complications.[61]

The essential point is that the FDA has neglected to consider any of these studies in developing a risk versus benefits assessment of mifepristone.

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[58] *Id.*

[59] *See* Sanne A. E. Peters et al., *Pregnancy, Pregnancy Loss, and the Risk of Cardiovascular Disease in Chinese Women: Findings from the China Kadoorie Biobank*, BMC Med., Aug. 2017, at ; Maka Tsulukidze et al., *Elevated Cardiovascular Disease Risk in Low-Income Women with a History of Pregnancy Loss*, Open Heart, June 9, 2022, at ; Harry Kyriacou et al., *The Risk of Cardiovascular Diseases After Miscarriage, Stillbirth, and Induced Abortion: A Systematic Review and Meta-Analysis*, European Heart J. Open, Oct. 5, 2022, at 1.

[60] Shuqing Zou et al., *Genetic and Lifestyle Factors for Breast Cancer Risk Assessment in Southeast China*, 12 Cancer Med. 15,504, 15, 507 (2023). Notably, most abortions in China during the time of the study were induced using mifepristone.

[61] For an annotated bibliography of peer reviewed studies identifying physical risks statistically associated with abortion, see *Physical Effects of Abortion*, Elliot Inst., tinyurl.com/AbPhysical (last visited Feb. 27, 2024).

C. Women Want to Be Informed of All Risks Associated with Elective Abortions. But the FDA Has Not Only Refused to Warn Against Use of Mifepristone in Contraindicated Cases, It Has Also Failed to Require Adequate Warnings on The Mifepristone Label.

Research into patient's preferences for information about risks reveals that women considering any elective treatment wish to be informed of every possible risk, even rare or unlikely ones.[62] When asked if their preference for risk disclosure would be higher or lower for abortion and other obstetric or gynecological treatments, as compared to other elective treatments in general, women on average reported a desire for more, not less, information when it comes to abortion.[63]

Despite these patient preferences, none of the risks associated with abortion identified in the previous section are listed on the mifepristone label.

These omissions violate the FDA's own standards which require warning of risks "as soon as there is *reasonable evidence of an association* of a serious hazard with a drug; a causal relationship need not have been proved." 21 C.F.R. § 201.80(e) (emphasis added).

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[62] Priscilla K. Coleman et al., *Women's Preferences for Information and Complication Seriousness Ratings Related to Elective Medical Procedures.*, 32 J. Med. Ethics 435, 437 (2006).
[63] *Id.*

IV. CLAIMS THAT "ABORTION BENEFITS WOMEN" AND THAT "WOMEN DENIED ABORTIONS WILL SUFFER HARMS" REST ON THE HIGHLY FLAWED TURNAWAY STUDY.

The professional societies advocating for more abortions routinely ignore the above-cited studies documenting harms linked to abortion. Instead, their "expert opinions" are based on an ideologically driven selective reading of the literature and reliance on laughably poor claims that abortion is almost always safe and beneficial.

For example, numerous briefs filed in support of the Petitioners have cited references to the Turnaway Study,[64] a project of the highly partisan population control group Advancing New Standards in Reproductive Health ("ANSIRH"). What these briefs fail to reveal is that the Turnaway Study is based on a small, non-random, non-representative sample of paid volunteers. In sum, its results cannot properly be generalized to the entire population of women seeking abortion.

Specifically, the Turnaway Study (a) excluded subsets of women at greatest risk of more negative emotional reactions, (b) had a 69% self-exclusion rate among the subset invited to participate, (c) had a 50% dropout rate during the course of the study, (d) inappropriately mixed women with a history of prior abortions into the group of women without a history of abortion, and (e) also mixed both women who carried to term and women who found late-term

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[64] Diana Greene Foster, *The Turnaway Study* (Scribner, 1st ed. 2020).

abortions elsewhere into their "women denied abortions" group.[65]

Subsequent research has demonstrated that the 69% of those who declined to participate in ANSIRH's post-abortion interviews were most likely from the 67% of women in retrospective studies who report feeling the highest degree of pressure to agree to unwanted abortions contrary to their own values and preferences.[66] These are exactly the women who are also at greatest risk of negative outcomes.[67]

Despite the Turnaway Study's fatal flaws, the American Psychological Association's latest fact sheet on abortion and mental health cites it as proof that women "denied an abortion reported more anxiety symptoms and stress, lower self-esteem, and lower life satisfaction than those who received one."[68]

This statement, however, is ideologically driven disinformation. A more careful reading of the cited Turnaway Study reveals that more anxiety and lower life satisfaction scores were limited *only to women still seeking abortions* and only *one week* after being turned away for being over the gestational limit.[69] The women who went on to carry to term *did not report* any negative mental health effects, neither one week later or over the five years

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[65] *Abortion and Mental Health Controversy*, *supra* note 37, at 18-19; David C. Reardon, *The Embrace of the Pro-Abortion Turnaway Study. Wishful Thinking? Or Willful Deceptions?*, 85 Linacre Q. 204, 208 (2018).

[66] *Effects of Abortion Decision Rightness*, *supra* note 5, at 4, 9.

[67] *Id.* at 9; *Effects of Pressure to Abort*, *supra* note 3, at 9.

[68] Zara Abrams, *The Facts About Abortion and Mental Health*, Monitor Psych., Sept. 2022.

[69] M. Antonia Biggs et al., *Women's Mental Health and Well-Being 5 Years After Receiving or Being Denied an Abortion a Prospective, Longitudinal Cohort Study*, 74 JAMA Psychiatry 169, 170 (2017).

investigated.[70] Instead, "women who were denied [abortions] were more likely to feel happiness about the pregnancy than women who received an abortion."[71]

Yet the APA statement implies that all those who were denied abortions and carried to term experienced negative outcomes, when in fact only those who were originally *denied* abortions yet subsequently *received abortions* reported negative outcomes at the one-week follow up interview.[72] This is not just misleading; it is disinformation.

Indeed, the lead Turnaway Study scientist subsequently admitted her surprise at being unable to prove there are any mental health harms associated with being denied an abortion:

> I expected that raising a child one wasn't planning to have might be associated with depression or anxiety. But this is not what we found over the long run. Carrying an unwanted pregnancy to term was not associated with mental health harm. Women are resilient to the experience of giving birth following an unwanted pregnancy, at least in terms of their mental health.[73]

She also reported that both immediately after being denied an abortion, and among those who remained in the study for the full five years, very few, if any reported that they still wished they had been able to have an abortion.[74]

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[70] Foster, *supra* note 64, at 109.
[71] *Id.* at 121.
[72] *Id.* at 109.
[73] *Id.*
[74] *Id.* at 204.

In short, the Turnaway Study conclusively established that an overwhelming majority (96%) of women who were denied abortions were grateful they never aborted their child.[75]

Despite these inconvenient truths, ANSIRH researchers have desperately tried to find negative effects that they can attribute to being denied an abortion. For example, they asked if women had changed their short and mid-term aspirations after being denied an abortion. Obviously, women delivering their babies made new plans centered on their families rather than their careers. But this change in aspirations due to changes in circumstances has repeatedly been interpreted by ANSIRH as a "harm" to women.[76]

ANSIRH also propagated other misleading claims about the economic effects associated with being denied an abortion. Without the consent of its Turnaway Study participants, ANSIRH obtained credit reports on each of the subjects, including those who had withdrawn from the study both before and after the first interview.[77] This was unethical and like all credit pulls, caused at least a small ding (of up to ten points) on each subject's credit score.[78] In any case, ANSIRH's retrospective analysis of the women's credit reports revealed that the average credit score for those with an additional child was 550 compared to 558 for those who had abortions. This 1.5%

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[75] *Id.*

[76] *Id.* at 166-70.

[77] *Id.* at 178; David Reardon, *How the Turnaway Study's Authors Unethically Violated Participant's Privacy, Damaged Their Credit Scores, and Has Misled the Public with a Non-Representative Sample, Selective Reporting, and Overstated Conclusion*, Zenodo (Feb. 20, 2024), http://tinyurl.com/3zypa3jn.

[78] Steve Bucci, *Why Does a Hard Inquiry Hurt Your Credit Score?*, CreditCards (Feb. 2, 2022), http://tinyurl.com/kjsrbdub.

difference has repeatedly been exaggerated to be conclusive evidence of economic harm caused by abortion denial.[79]

But ANSIRH's claims about economic harms, and indeed every one of their findings, are actually meaningless precisely because their non-random sample is not representative of the general population of women having abortions, much less of those who might be protected from unwanted abortions by new state laws.

Moreover, even the "economic hardships" associated with having a newborn child after abortion denial, which they report, are most properly interpreted as simply reflecting the fact that families with one more child have more expenses. There is nothing surprising about that. But since their own data also shows these families mostly claim, by a far margin, that they are happy with their now loved child,[80] these additional expenses are clearly worth it.

It is important to recall that the Turnaway Study used a non-random, non-representative sample of women. Its design and inherent bias was toward underrepresenting the women who either anticipated or subsequently experienced negative reactions attributed to their abortions.[81]

Yet even with this optimized sample bias, ANSIRH still found high rates of sadness (64%), guilt (53%), regret (41%), and anger (31%) among women who had abortions, which in every case were higher than the same emotions among the women who

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[79] Foster, *supra* note 64, at 174-77; *see also* Reardon, *supra* note 77.

[80] Foster, *supra* note 64, at 109-26.

[81] *Effects of Abortion Decision Rightness*, *supra* note 5.

carried to term.[82] In addition, ANSIRH also found that 16% of their aborting women reported at least three symptoms of PTSD, of whom 19% attributed their symptoms to their abortions.[83]

How many of these facts will this Court find in the pro-abortion briefs citing the Turnaway Study? None. Why? Precisely because abortion proponents, like ANSIRH researchers, consistently cherry-pick the evidence they report, even from their own biased studies.

Finally, there is the matter of "relief." It is a very common strategy for ANSIRH, the APA, and other abortion proponents to hide all the negative emotions following abortion behind the misleading claim that the most common reaction to abortion is "relief," which was reported by 83% of the Turnaway Study abortion sample.[84]

But they fail to mention that this measure of "relief" is poorly defined. Women who report relief are being presented with a single word which encompasses a wide range of meanings. It includes relief that a dreaded medical procedure is over. Relief that one's partner will stop pressuring for an abortion. Relief that one's parents will not learn of the pregnancy. Relief that one will not need to find a bigger house. Relief that one can simply focus on something else in the future.

Given this catch-all word "relief," nearly all women will experience at least some relief.[85] This is precisely

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[82] Corinne H. Rocca et al., *Women's Emotions One Week After Receiving or Being Denied an Abortion in the United States*, 45 Persps. Sexual Reprod. Health 122, 126 (2013).

[83] M. Antonia Biggs et al., *Does Abortion Increase Women's Risk for Post-Traumatic Stress? Findings from a Prospective Longitudinal Cohort Study*, BMJ Open, Feb. 2016, at 7.

[84] Rocca et al., *supra* note 82.

[85] *Abortion and Mental Health Controversy*, *supra* note 37, at 19.

because abortion is almost always both a stress releaser and a stress creator.[86] It typically exchanges release of immediate stresses for a set of new stressors.[87] This is why most women who report positive emotions also report concurrent negative emotions.[88]

Pro-abortion researchers recognize this and will admit it when pressed. But if given the option, they prefer to hide these inconvenient truths behind the disingenuous claim that "'relief' is the most common reaction to abortion."[89]

Amici encourage the Court to see through the false claim that there is any meaningful scientific evidence that denial of abortion harms women. Such claims are based on a web of poor studies of a non-representative sample of women explicitly designed to support such disinformation. They also completely ignore the evidence, even from their own studies, that women who welcome unplanned pregnancies after being denied an abortion are overwhelmingly happy to have the resulting children in their lives.[90]

The simple and undisputed fact is that most women who experience abortions report a mix of emotions, including relief, but overall negative emotions are significantly more prominent than positive emotions,[91] and on average, women believe their abortions caused more harm than good to their mental health.[92]

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[86] *Id*. at 12.
[87] *Id*.
[88] *Id*.
[89] *Id*. at 19.
[90] Foster, *supra* note 64, at 109.
[91] *Abortion and Mental Health Controversy*, *supra* note 37, at 2.
[92] *Effects of Pressure to Abort*, *supra* note 3, at 8.

V. THE FDA DID NOT DEVELOP AN EVIDENCE-BASED RISK VERSUS BENEFITS ASSESSMENT IDENTIFYING WHEN, IF EVER, MIFEPRISTONE IS A MORE EFFECTIVE AND SAFER OPTION TO BOTH (A) SURGICAL ABORTION AND (B) CONTINUING A PREGNANCY.

The FDA excused the manufacturers of mifepristone from undertaking a double-blind placebo-controlled trial of their drug by offering them "accelerated approval" under 21 C.F.R. § 314.500, which allows approval of "new drug products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients *over existing treatments*."[93]

But pregnancy is not an illness, and rarely life-threatening, at least in modern times.

Indeed, throughout history, most pregnancies have been unplanned and even initially unwanted. But as even ANSIRH's lead scientist has admitted, women are resilient and most often quick in adjusting to and welcoming unplanned pregnancies.[94] In fact, most of the women who sought abortions and were turned away reported that they soon welcomed and loved their children.[95]

In short, the drug should only have been approved if it had been proven to provide "meaningful therapeutic benefit" relative to each and every one of these alternatives.

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[93] 21 C.F.R. § 314.500 (emphasis added).
[94] Foster, *supra* note 64, at 109.
[95] *Id.* at 204.

Under the FDA's own guidelines,[96] mifepristone should have been approved by the FDA only when:

- there is clear statistically validated evidence (normally from a double-blind placebo-controlled trial) that the drug is the *direct cause* of one or more benefits that are real, measurable and statistically significant, not just theoretical,
- the observed benefits are greater than the associated risks,
- the risks of the drug have been minimized, and
- there is adequate risk management in the form of warnings and safeguards to prevent use of the drug in any contraindicated cases, specifically in cases where the risks are more likely to exceed the proven benefits.

The last point is especially important. It is common for drugs which may be effective in some cases to be deadly in others, for example, when a patient has known risk factors, such as diabetes.

In the specific case of abortion, the American Psychological Association has identified at least fifteen risk factors, including feeling pressured into an unwanted abortion.[97] Therefore, according to the FDA's normally applied standards, women who *do not have any of these risk factors* should be identified, as the only "subpopulation . . . for whom the benefits outweigh the risks, even if they [the benefits] do not do so [outweigh the risks] in a broader population, and then targeting the drug's labeled indication to that [sub]population."[98]

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[96] *See generally* Food and Drug Administration, *Benefit-Risk Assessment for New Drug and Biological Products Guidance for Industry* (2023), https://www.fda.gov/media/152544/download.
[97] *Abortion and Mental Health Controversy*, *supra* note 37, at 3.
[98] Food and Drug Administration, *supra* note 96, at 4.

Absent clear and compelling evidence that the benefits versus risks assessment for mifepristone was superior to both surgical abortion and continuing a pregnancy, mifepristone should not have been approved, nor its use expanded.

It is also worth repeating that the FDA's standard for proving direct causal connection to benefits is normally higher than the standard used to identify possible risks.[99]

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Amici include post-abortion counselors, and academics who have studied the negative effects of abortion identified in tens of millions medical records, random retrospective studies, nationally representative surveys, and thousands of individual self-reports.

We know, as a matter of fact—not just opinion—that under the FDA's watch literally millions of women have been subjected to unwanted and unsafe drug induced abortions. Specifically, the FDA has simply ignored the fact that there are clear contraindications for abortion, including the fifteen risk factors identified by the American Psychological Association.

Cheaper and more readily available abortion drugs are a double-edged sword. On one hand, the 33% of women who reportedly freely want abortions, in accord with their own values and preferences, enjoy easier access. On the other hand, the 67% who agree to abortions contrary to their own preferences due to

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[99] 21 C.F.R. § 860.7(c)(2) notes that "[i]solated case reports, random experience[s]" and less well documented effects "are not required" in evaluating efficacy but "may be considered" in evaluating risks.

pressures they face are more easily victimized. The latter effect was at least partially the public policy objective identified in Ron Weddington's letter to President Clinton, wherein he argued that FDA approval of abortion drugs was essential to the goal of eliminating "the barely educated, unhealthy and poor segment of our country."[100]

In service of this public policy objective, the FDA shirked its duty to protect the American people from unsafe and unnecessary drugs. There is simply no evidence that mifepristone is the direct cause of any physical or psychosocial benefits to women in general, or even specific subsets of women. Conversely, there is abundant evidence that abortion, by any means, contributes to physical and psychosocial harms—especially for the vast majority of abortion patients who have one or more of the identified risk factors for post-abortion sequalae.

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[100] Letter from James R. Weddington to President-To-Be Clinton, *supra* note 11, at 1.

CONCLUSION

This Court should affirm the judgment of the Fifth Circuit.

Respectfully submitted,

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February 29, 2024