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

BRIEF OF *AMICUS CURIAE* STANTON INTERNATIONAL IN SUPPORT OF RESPONDENTS

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February 29, 2024

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STATEMENT OF IDENTITY AND INTERESTS OF *AMICUS CURIAE*

Pursuant to Supreme Court Rule 37, *Amicus Curiae*, Stanton International, submits this brief.[1] *Amicus Curiae* provides caring solutions which uphold the dignity of both mother and child. Stanton International believes that women deserve better, more compassionate, and higher quality alternatives to the abortion clinic and coercive abortion tactics of the past. In 2006, Brandi Swindell founded Stanton International in Meridian, Idaho. Almost two decades later, Stanton International has provided premiere wellness care for women considering abortion in Idaho through services including ultrasounds, pregnancy tests, client advocacy and life-affirming programs, resources, and counseling. Stanton International's licensed medical professionals and trained client advocates are devoted to professional, compassionate, and confidential care, marked by excellence. Stanton International holds accreditation from the Association for Ambulatory Heath Care. Stanton International provides all of its services to clients at no cost.

In addition to Stanton International's flagship clinic in Idaho, its healthcare services have expanded into multiple states, two additional countries, and the organization launched Stanton Mobile, which provides critical medical services and resources to universities,

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[1] No counsel for any party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *Amicus*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

refugee communities, and other under-served locations around the Treasure Valley in Idaho and beyond.

A Senate Committee asked Brandi Swindell to share testimony regarding the life changing work that Stanton International successfully implements. https://www.youtube.com/watch?v=_TlnldIHagA&t=233s. During the hearing, she shared, with the permission of the Stanton client, this feedback:

> I was in a very bad place in my life when I decided to get an abortion.
>
> My mom told me she wouldn't have anything to do with my baby. My boyfriend was a drug addict and causing abuse in my life and left me, and I was diagnosed with having severe panic attacks and hyperemesis at just 5 weeks into my pregnancy. I was so sick I would throw up 20-30 times a day and had to get IV fluids. I thought there was no way I could do this. I was so sick I felt like I could die. I already had one daughter and didn't think anyone would love me with two. I thought my only option to have a future was to abort my baby.
>
> I drove to Planned Parenthood and saw Stanton Healthcare across the parking lot. I had heard about them and thought to myself, "I'm going to go in there and if they can help me and can change my

> mind about getting an abortion, then so be it. And if not, I'm going across the parking lot to Planned Parenthood to get an abortion."
>
> I went to Stanton Healthcare and found that they are a real clinic that helped me with everything I needed. They loved me and showed me I wasn't alone, gave me things I needed for my baby, counseling to get out of my life-threatening abusive relationship, encouraged me I could make it through having hyperemesis, encouraged me that I could have a life with this baby, encouraged me to find a church [where] I was loved after having been hurt elsewhere, and gave me ultrasounds to see my baby. Seeing my daughter's heartbeat made me stop feeling the panic attacks that made me want to abort and stop feeling the horrible nausea and see my baby was a real person that I couldn't kill. It instantly made me feel attached to my baby and love her.

https://www.help.senate.gov/imo/media/doc/Swindell.pdf. Stanton International serves women and children, many times saving both and altering the trajectory of their lives from a place of hardship to one of hope. https://stantoninternational.org/stories-of-hope/.

Amicus Curiae has worked for nearly twenty years providing healthcare and solutions to women. Stanton International has tirelessly devoted its time and resources to making pregnancy choices healthy, safe, and empowering for women and their children by creating a community of hope and a landscape in which they invest in women and help them overcome and identify challenges to achieve long-term success. *Amicus Curiae* has counseled numerous women harmed, both physically and mentally, by the negative effects of mifepristone (the abortion pill). Clients of Stanton International have shared their testimony of receiving the abortion pill through telehealth appointments without proper medical advice or support. *Amicus Curiae*'s clients have experienced isolation, regret, and what, for any other medical procedure, would quickly be deemed malpractice. *Amicus Curiae* files this brief to inform this Honorable Court of the harm that women experience through the United States Food and Drug Administration's (FDA's) decision to lower its standards for the abortion pill and encourage this Court to uphold the Fifth Circuit's rulings.

SUMMARY OF THE ARGUMENT

The FDA knows the risks that the abortion pill poses to the health and safety of pregnant women. Yet, even in the face of these known risks, it eliminated its standards, put in place to protect pregnant women, in favor of supporting a political goal of expanding abortion access. The FDA's actions are unsafe, and as experienced by *Amicus Curiae*, impose dangerous conditions on pregnant women that lack

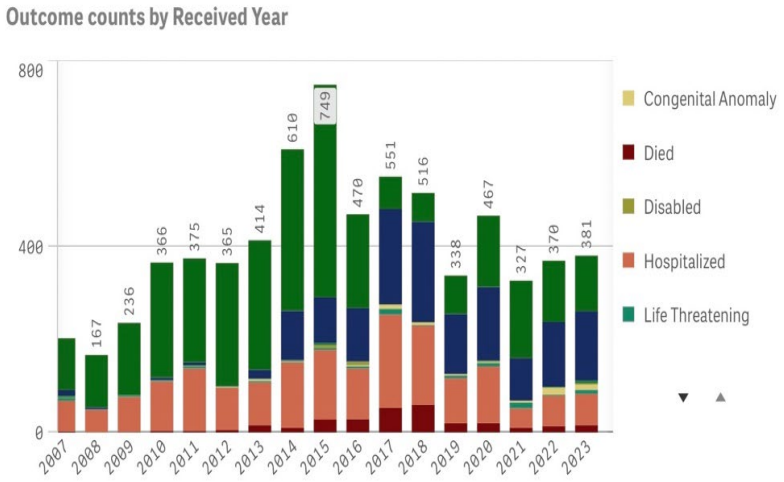
any semblance of safe, quality healthcare. Given the real implications for pregnant women in this country and that the FDA's decision rests, not on scientific standards but adherence to a pro-abortion political agenda, this Court should affirm the Fifth Circuit's decision in full.

ARGUMENT

"This case involves one of the most troubling public health problems facing our Nation today": the devaluation of the wellbeing, safety, and dignity of a woman because she is pregnant. *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000). The FDA is well aware of the abortion pill's risk of serious complications and death. *See* https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_REMS_Full.pdf, last visited Fed. 29, 2024. Yet, in the face of these known risks, the FDA decided to deplete its health and safety standards in the name of abortion expediency. No other medication without an in-person dispensing requirement carries such an elevated risk of serious complications or death.

The FDA reports that the abortion pill has caused life threatening injuries and hospitalization each year since its approval. FDA's Adverse Events Reporting System (FAERS), Mifepristone, https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/8eef7d83-7945-4091-b349-e5c41ed49f99/state/analysis, last visited Feb. 29, 2024. The FDA admits that the abortion pill causes disability and death. *Id.*

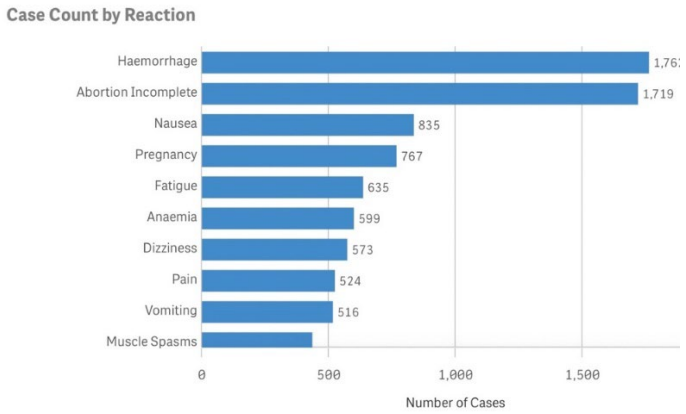
a. Table 1, FAERS's Mifepristone Outcome Counts of Adverse Events by Year Received:[2]



FDA records indicate that the most common adverse event associated with the abortion pill is hemorrhage, or excessive bleeding. *Id*.

[2]https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/8eef7d83-7945-4091-b349-e5c41ed49f99/state/analysis, last visited Feb. 29, 2024.

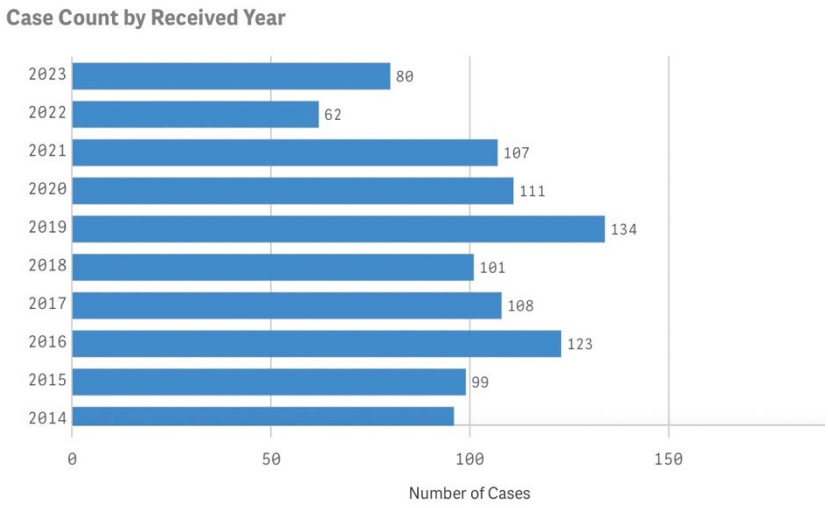
b. Table 2, FAERS's Mifepristone Case Count by Reaction:[3]



Compare the severity of the FDA's reported adverse events associated with the abortion pill to a more representative, typical prescription that does not require in person dispensing. Macrobid, for example, is prescribed to woman to treat bacterial infection, and is even prescribed during the first trimester of pregnancy. *See, e.g.*, https://www.cdc.gov/mmwr/volumes/67/wr/mm6701a4.htm, last visited Feb. 29, 2024. Macrobid's case count per year is significantly less than that of the abortion pill, greater than 90% less. https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4/state/analysis, last visited Feb. 29, 2024.

[3] *Id.*

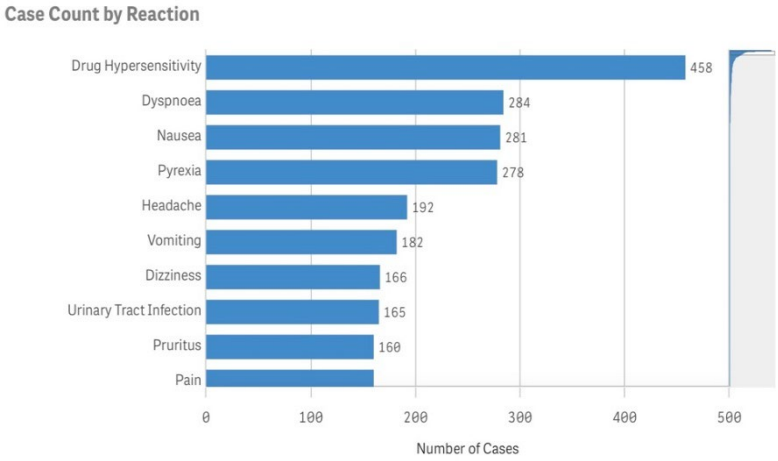
c. Table 3- FAER's Macrobid's Case Count by Year Received:[4]



In addition to far fewer cases, the types of cases reported are also far less serious. Macrobid's FAERS reflects more mild side effects, such as drug hypersensitivity (commonly rash or photosensitivity), nausea, or headache. https://www.mayoclinic.org/drugs-supplements/nitrofurantoin-oral-route/side-effects/drg-20065102, last visited Feb. 29, 2024. Such side effects pale in comparison to the abortion pill's high risk of life-threatening complications, hospitalization, and death due to hemorrhage or incomplete abortion. *Compare* Table 1 to Tables 3 and 4.

[4] *Id.*

d. Table 4- FAER's Macrobid Case County by Reaction:[5]



Outside of the abortion pill, the FDA approves no other prescription for in person dispensing that imposes such risk of a life-threatening adverse events, hospitalization, or death. *See* Table 1. Per the FDA, the abortion pill fails up to 7% of the time. *See* FDA Mifepristone Patient Agreement Form at ¶ 6, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_Patient_Agreement_Form.pdf, last visited Feb. 29, 2024. And it puts pregnant women at risk for serious and deadly health complications—due not only to the risk of the drug itself but also due to the heightened risk associated with foregoing any type of screening or ultrasound by the FDA's approval of the remote dispensing of the abortion pill (conditions that were required during the FDA's initial approval of the drug to prevent unnecessary complications due to ectopic pregnancy and to avoid risk from the serious side effects of the

[5] *Id.*

drug). *See All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 78 F.4th 210, 224 (5th Cir.), *cert. granted sub nom. Food & Drug Admin. v. All. for Hippocratic Med.*, 144 S. Ct. 537 (2023), and *cert. granted sub nom. Danco Lab'ys, L.L.C. v. All. for Hippocratic Med.*, 144 S. Ct. 537 (2023), and *cert. denied sub nom. All. for Hippocratic Med. v. Food & Drug Admin.*, 144 S. Ct. 537 (2023). Even with screenings to determine the gestational age of the women's pregnancy and an ultrasound to ensure that she is not carrying an ectopic pregnancy, the FDA's known data expresses that "between 2.9% and 4.6% of women" would require emergency care after taking the abortion drug. *All. for Hippocratic Med.*, 78 F.4th at 230. This statistic is consistent with the data that was known to the FDA in its 2000 approval memorandum citing that the abortion pill required surgical intervention for 7.9% of women who took the drug. *Id.* But without any screening for gestational age, ultrasound, or even one in-person meeting, all formerly required prior to dissemination of the abortion pill, the harm reflected in these statistics will assuredly only increase.

I. The FDA's Handling of the Abortion Pill Causes Significant Harm to Women and Children and Has a Far-reaching Effect on Everyone Who Cares for Them.

Amicus Curiae is personally aware of the harm caused by the abortion pill and the real-life effects of the FDA's relaxation of its standards, which may benefit the goal of unfettered access to abortion but fails to benefit and in no uncertain terms puts at risk

the health and safety of pregnant women. Shortly after this Court decision in *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022), *Amicus Curiae* received a phone call from a client who had been coerced to seek an abortion by her boyfriend. https://www.youtube.com/watch?v=TBL6z70cf3E, last visited Feb. 29, 2024 (beginning at 13:19, describing the experience of an "Abortion in a McDonald's Parking Lot"); *see also* https://www.liveaction.org/news/swindell-women-post-roe-america/, last visited Feb. 29, 2024. *Amicus Curiae*'s client described how Planned Parenthood coached her to drive across state lines to Ontario, Oregon where she, per their instructions, parked her car in the parking lot of a McDonald's. *Id.* Once in the parking lot, Planned Parenthood instructed her to place a phone call, which was considered a telehealth appointment, permitting her to obtain the abortion pill without any other precautions or screenings. *Id.* After the phone call from the McDonald's parking lot, *Amicus Curiae*'s client received instructions to drive to a FedEx Drop-off point where she obtained the abortion pill. *Id.* Acting on the coercive pressure of her boyfriend to proceed with the abortion, the client took the abortion pill but experienced immediate regret for doing so and contacted *Amicus Curiae* for support and help. *Id.* *Amicus Curiae*'s client never received any adequate counseling regarding options for her pregnancy, or counseling to ensure that her desire to obtain an abortion was not coerced, nor was she properly screened or counseled regarding the effects of the abortion pill. *Id.* After learning what she desired for her pregnancy, it was clear that she did not want the abortion at all. *Id.* *Amicus Curiae*

assisted their client without delay, and a physician's assistant was able to prescribe progesterone to reverse the effects of the depletion of progesterone caused by the abortion pill. *Id.* *Amicus Curiae*'s client gratefully carried her son to term, while receiving full-scale support from *Amicus Curiae*. *Id.* Her son was born healthy:

Both she and her baby are now thriving. *Id.* This actual account of how the abortion pill is disseminated exhibits the clear lack of effective health and safety standards imposed by the FDA's current regulations. The abortion pill can be disseminated after one phone call that, per Planned Parenthood's instructions, takes place in a McDonald's parking lot with no assurances or medical diagnostics to ensure the woman taking the pill is pregnant, is carrying a pregnancy of a certain gestational age, or has any significant risk factors, such as an ectopic pregnancy. This protocol is plainly

unsafe, ill-advised, and requires the intervention of this Court.

II. This Court Can, and Should, Correct the FDA's Arbitrary and Capricious Actions That Put at Risk the Health and Safety of Pregnant Women.

The abortion pill's risk of serious harm makes it an obvious outlier for the FDA to eliminate its in-person dispensing requirements. Furthermore, the decision flies in the face of the FDA's previous determinations and its scientific studies regarding the safe dissemination of the drug. So why did the FDA alter its 21-year protocol regarding the abortion pill? The answer is motivated solely by politics, and not by "good faith" or "reasoned agency decision-making." *Tummino v. Torti*, 603 F. Supp. 2d 519, 523 (E.D.N.Y. 2009), amended sub nom. *Tummino v. Hamburg*, No. 05-CV-366 ERK VVP, 2013 WL 865851 (E.D.N.Y. Mar. 6, 2013).

On September 1, 2021, this Court denied a stay of the Texas Heartbeat Act which prohibited a physician from performing an abortion on a pregnant woman after her unborn child's heartbeat was detected. *Whole Woman's Health v. Jackson*, 595 U.S. 30 (2021). In response, President Biden issued a statement vowing to protect the right to abortion. https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/01/statement-by-president-joe-biden-on-texas-law-sb8/, last visited Feb. 29, 2024; *see also* https://www.cnn.com/2021/09/03/politics/biden-texas-

abortion-law/index.html, last visited Fed. 29, 2024 (explaining that he is launching a "whole government" effort to respond to the ruling to expand abortion access). This "whole government" response included the FDA, who has once again "bowed to political pressure from the White House" on December 16, 2021, when it eliminated health and safety protections for pregnant women in favor of assuaging the President's stated political goal of expanding abortion access. *Id*. at 538. The FDA acted according to "political pressure rather than permissible" sound health and safety standards. *Tummino*, 603 F. Supp. 2d at 548. Pregnant women deserve better than this.

CONCLUSION

The slack the FDA arbitrarily and capriciously loosened on its procedural and substantive safeguards of the abortion pill cause real and lasting harm to women, children, and the people who care for them. This Honorable Court should affirm the decision of the Fifth Circuit and remand for further proceedings.

Respectfully submitted,

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