Nos. 23-235, 23-236

In the Supreme Court of the United States

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 *AMICI CURIAE* OF ___ MEMBERS OF CONGRESS IN SUPPORT OF RESPONDENTS AND AFFIRMANCE

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Table of Contents

Table of Authorities

Statement of Interest of *Amici Curiae*[1]

Amici are ___ Members of the United States Congress, ___ Senators and ___ Members of the House of Representatives, representing ___ States. A complete list of *Amici* is found in the Appendix to this brief. Congress authorizes power to the U.S. Food and Drug Administration (FDA) to approve drugs and regulate their safety and efficacy. 21 U.S.C. § 393. Congress directs administrative agencies to act within the scope of their authorized powers. 5 U.S.C. § 706; *see Skinner v. Mid-America Pipeline Co.*, 490 U.S. 212, 218 (1989) (citing *Mistretta v. United States*, 488 U.S. 361, 379 (1989)) (There is a "longstanding principle that so long as Congress provides an administrative agency with standards guiding its actions such that a court could 'ascertain whether the will of Congress has been obeyed,' no delegation of legislative authority trenching on the principle of separation of powers has occurred.").

As pro-life elected representatives, *Amici* are committed to protecting women and adolescent girls from the harms of the abortion industry. By deregulating chemical abortion drugs, the FDA failed to follow Congress' statutorily prescribed drug approval process to the detriment of patient welfare. The FDA's lawless actions ultimately have

[1] No party's counsel authored any part of this brief. No person other than *Amici Curiae* and their counsel contributed any money intended to fund the preparation or submission of this brief.

endangered women and girls seeking chemical abortions.

Summary of Argument

Congress has carefully considered the approval process for new drugs, instituting safeguards to protect patients' welfare. The Federal Food, Drug, and Cosmetic Act (FDCA) seeks to ensure new drugs are safe and effective for patients. 21 U.S.C. § 355. Congress has also decreed that abortion-inducing drugs are "nonmailable matter" and prohibited their shipment by the United States Postal Service and common carriers, protecting women and girls from the heightened risks of mail-order chemical abortion drugs. 18 U.S.C. §§ 1461–1462.

The FDA subverted these patient safeguards when deregulating mifepristone. The "chemical abortion pill" is a regimen of two drugs, mifepristone and misoprostol.[2] "[M]ifepristone (brand name, Mifeprex), is an antiprogesterone, which starves the [unborn child]. The second, misoprostol (brand name, Cytotec), a prostaglandin, causes the uterus to contract, which mechanically expels the fetus and placenta." Clarke D. Forsythe & Donna Harrison, *State Regulation of Chemical Abortion After* Dobbs, 16 Liberty U. L. Rev. 377, 377 (2022). In 2016, the FDA

[2] *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. Food & Drug Admin. (Sept. 1, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

eliminated patient safeguards such as by "[r]emoving the requirement that the administration of misoprostol and the subsequent follow-up appointment be conducted in person[, and e]liminating prescribers' obligation to report non-fatal adverse events." *All. for Hippocratic Med. v. Food & Drug Admin.*, 78 F. 4th 210, 225 (5th Cir. 2023). In 2021, the FDA removed the in-person dispensing requirement, which "allowed mifepristone to be prescribed remotely and sent via mail." *Id.* at 226. The Fifth Circuit affirmed a stay of the FDA's 2016 and 2021 actions since the actions likely violated the Administrative Procedure Act (APA). *Id.* at 222–223.

The APA ensures federal agencies stay within the scope of their congressionally authorized power. Under the APA, federal administrative agencies have no authority to act arbitrarily and capriciously "or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). As this Court has acknowledged:

> Congress did not set agencies free to disregard legislative direction in the statutory scheme that the agency administers. Congress may limit an agency's exercise of enforcement power if it wishes, either by setting substantive priorities, or by otherwise circumscribing an agency's power to discriminate among issues or cases it will pursue.

Heckler v. Chaney, 470 U.S. 821, 833 (1985). Accordingly, the FDA must adhere to patient

safeguards within federal laws when deregulating drugs.

Amici agree with Respondents that they have standing to challenge the FDA's unlawful deregulation of mifepristone in this case. *Amici* write separately to contribute a federal policy perspective as to why the FDA, in deregulating mifepristone, acted arbitrarily and capriciously in violation of the APA, by (I) subverting its obligations under the FDCA to ensure new drugs are safe and effective; and (II) blatantly disregarding the federal law's prohibition on the mailing and interstate shipment of abortion-inducing drugs. Since the FDA's lawless deregulation of mifepristone subverts patient safeguards and contravenes federal laws, *Amici* urge the Court to affirm the Section 705 stay of the FDA's 2016 and 2021 actions.

Argument

I. THE FDA'S FAILURE TO ADHERE TO THE FDCA HAS CREATED SIGNIFICANT HEALTH AND SAFETY RISKS TO WOMEN AND GIRLS.

The FDA exceeded its congressionally authorized power when it deregulated mifepristone in 2016 and 2021. Mifepristone carries significant risks for women and girls, and the FDA exacerbated these risks by unlawfully deregulating chemical abortion drugs.

A. The FDA Subverted Patient Safeguards in the FDCA.

Congress placed safeguards within the FDCA to ensure new drugs are safe and efficacious for patients. 21 U.S.C. § 355. If the sponsor of an FDA-approved drug wants to change the way the drug is labeled, marketed, or manufactured, it is required to submit a supplemental new drug application, which is subject to the FDA's approval. *Id*. at § 355(b); 21 C.F.R. §§ 314.54 (2016), 314.70 (2016). The application must meet patient safeguards, but fails to do so when:

> the investigations . . . do not include adequate tests . . . to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling; . . . [there is] insufficient information to determine whether the drug is safe for use under such conditions; or . . . there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

21 U.S.C. § 355(d). If the application does not meet these patient health and safety standards, the FDA Secretary "shall issue an order refusing to approve the application." *Id*.

The FDA's removal of patient safeguards in 2016 and 2021 run contrary to the FDCA's requirements

because these actions further jeopardize patients' welfare. Since 2016, the FDA has only required adverse events reporting for deaths resulting from chemical abortion drugs; reporting is otherwise voluntary. *All. for Hippocratic Med.*, 78 F. 4th at 225. This action was not only arbitrary and capricious, but it also raised safety concerns for women seeking chemical abortion drugs. As the Fifth Circuit noted:

> When considering the data-collection question, FDA reasoned that non-fatal adverse events did not have to be recorded because the risks associated with mifepristone were well known. But FDA failed to account for the fact that it was about to significantly loosen mifepristone's conditions for use. At no point during the decisions did the agency acknowledge that the 2016 Amendments might alter the risk profile. And when FDA addressed this subject in its response to the 2019 citizen petition, it just referred back to its statement that the risks were minimal under the 2011 REMS.

Id. at 246–247 (citations omitted). Consequently, the FDA is working with incomplete data about mifepristone's risks. As one study concludes, "FAERS [the FDA Adverse Event Reporting System] is inadequate to evaluate the safety of mifepristone" due to reporting discrepancies, and the fact that the FDA no longer mandates reporting of non-lethal adverse events. Christina A. Circucci et al., *Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse*

Event Reporting System and Those Obtained Through the Freedom of Information Act, Health Servs. Rsch. & Managerial Epidemiology, Dec. 21, 2021, at 1, 4. Even so, the FDA has received FAERS Mifeprex reports between September 28, 2000 to December 31, 2022 documenting 32 deaths (regardless of causality), 4,218 adverse events, 1,049 hospitalizations (excluding deaths), 604 blood loss incidents requiring transfusions, 418 infections, and 75 severe infections. *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2022*, U.S. Food & Drug Admin. 1, 1–2 (Dec. 31, 2022), https://www.fda.gov/media/164331/download.

The FDA also lacks data on the cumulative effect of the 2016 changes. As the Fifth Circuit found, the "FDA did not consider the cumulative effect of the 2016 amendments . . . . FDA admits that none of the studies it relied on examined the effect of implementing all of those changes together. It studied the amendments individually." *All. for Hippocratic Med.*, 78 F. 4th at 246. Accordingly,

> [t]he problem is not that FDA failed to conduct a clinical trial that included each of the proposed changes as a control. It is that FDA failed to address the cumulative effect at all. At a minimum, the agency needed to acknowledge the question, determine if the evidence before it adequately satisfied the concern, and explain its reasoning. FDA did not do those things, and so likely violated the APA.

Id. at 246 (citation omitted). Thus, the FDA's 2016 actions exceeded the scope of the authority Congress conferred to the FDA.

The FDA's 2021 deregulation only compounded the data issue. Again, the FDA eliminated non-fatal adverse event reporting data in 2016, so it "no longer had access to perhaps the best source of data: the prescribers." *Id*. at 249. Regardless, the FDA relied upon the FAERS data when concluding it was safe to remove the in-person dispensing requirement, even though it is arbitrary and capricious for the agency to "cite its lack of information as an argument in favor of removing further safeguards." *Id*.

Without adequate data, the FDA relied on literature that was "not inconsistent with [its] conclusion" that medical professionals can prescribe mifepristone safely without the in-person dispensing requirement. *Id*. at 250 (citing 2021 Denial Letter at 28) (alteration in original). "In other words, the studies neither confirmed nor rejected the idea that mifepristone would be safe if the in-person dispensing requirement were removed." *Id*. Yet, voluntary non-lethal FAERS data and literature that is "not inconsistent" with the FDA's assertion that medical professionals can safely prescribe mifepristone without in-person dispensing is "insufficient information to determine whether such drug is safe for use under such conditions." 21 U.S.C. § 355(d)(4). Thus, the FDA acted outside the scope of its authority when it deregulated mifepristone in 2016 and 2021.

B. Chemical Abortion Drugs Carry Significant Risks for Women and Girls.

By removing patient safeguards in 2016 and 2021, the FDA's lawless actions have victimized women and girls seeking these drugs. Unfortunately, "the medical community knew what American women would soon learn by experience," that chemical abortion drugs pose significant risks. Staff of Subcomm. on Crim. Just., Drug Pol'y and Hum. Res. of the H. Comm. on Gov't Reform, 109th Cong., *The FDA and RU-486: Lowering the Standard for Women's Health* 13 (Subcomm. Print 2006) "[M]ifepristone interferes with the body's immune response . . . is more inconvenient than surgical abortion . . . is more painful . . . is less effective . . . is associated with more adverse events . . . [and] causes more frequent and more severe hemorrhage than its surgical counterpart." *Id*. at 13–14.

Fundamentally, chemical abortion drugs pose serious health and safety risks to women and girls. There is an "assumption that [a chemical abortion] is more natural, private and safer than a surgical procedure, but physicians and patients alike may be unaware that it takes much longer, involves far more bleeding and pain, and complications occur four times more frequently from medical as compared to surgical abortions." Rsch. Comm., Am. Ass'n Pro-Life Obstetricians & Gynecologists, *Medication Abortion*, Prac. Guideline No. 8, at 3 (Feb. 2020). According to the FDA label, women "experience vaginal bleeding or spotting for an average of 9 to 16 days. . . . Up to 8%

of women may experience some type of bleeding for more than 30 days." *Mifeprex Prescribing Information*, U.S. Food & Drug Admin. 4 (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf. Unfortunately, "[t]he side effects of cramping, vaginal bleeding, hemorrhage, nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness occur in almost all women." Rsch. Comm., *Medication Abortion*, *supra*, at 3. As the gestational age increases, so too will the complication rates for women taking chemical abortion drugs. *Id*.

The FDA acknowledges that "MIFEPREX is available only through a restricted program under a REMS called the mifepristone REMS Program, because of the risks of serious complications," including infection, sepsis, and excessive uterine bleeding. *Mifeprex Prescribing Information*, *supra*, at 5–6. The FDA label notes clinical studies had 2.9 to 4.6% of women visit the emergency room following the administration of chemical abortion drugs. *Id*. at 8. Accordingly, the FDA requires chemical abortion providers to "inform the patient about the risks of these serious events[, and e]nsure that the patient knows whom to call and what do, including going to an Emergency Room" in case of complications. *Id*. at 2.

U.S. abortion studies have reported lower chemical abortion complication rates than statistics found in international scientific studies. *Id*. at 7. For example, studies from Scandinavian countries, which

record pregnancy and medical events through a national registry, give a better picture of chemical abortion complications than U.S. data. In a study of 42,619 Finnish women receiving chemical abortions up to nine weeks gestational age, the overall adverse events were almost fourfold higher in chemical (20.0%) versus surgical abortions (5.6%). Maarit Niinimaki et al., *Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology 795, 795 (2009). Women hemorrhaged more commonly after chemical abortion (15.6% compared with 2.1%). *Id.* They also had incomplete abortions more often in chemical abortions (6.7% versus 1.6%). *Id.* The rate of surgical (re)evacuation was higher after chemical abortions (5.9%) than surgical abortions (1.8%). *Id.*

Another study examined first and second trimester chemical abortions of 18,248 Finnish women. Maarit J. Mentula et al., *Immediate Adverse Events After Second Trimester Medical Termination of Pregnancy: Results of a Nationwide Registry Study*, 26 Hum. Reprod. 927, 927 (2011). Women undergoing first and second trimester chemical abortions needed surgical evacuation in 9.9% of cases. *Id.* at 929. Women specifically undergoing second trimester chemical abortions needed surgical evacuation in 39% of cases. *Id.* at 931. Later in pregnancy, the likelihood of serious complications significantly increases, something that cannot be controlled for when drugs are sent through the mail and taken without medical oversight.

Another concerning aspect of the FDA's deregulation of chemical abortion drugs is that it "entirely failed to consider an important aspect of the problem," *Motor Vehicle Mfrs. Ass'n v. State Farm Mutal Automobile Ins. Co.*, 463 U.S. 29, 43 (1983), such as the evidence of the drugs' psychological effects.[3] Abortion poses mental health risks for women and girls. "Pregnancy loss (natural or induced) is associated with an increased risk of mental health problems." 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, 1

Scholarship shows "that the emotional reaction or grief experience related to miscarriage and abortion can be prolonged, afflict mental health, and/or impact intimate or parental relationships." *Id.* Similarly, "[s]everal recent international studies have demonstrated that repetitive early pregnancy loss, including both miscarriage and induced abortions, is associated with increased levels of distress,

[3] *See* David C. Reardon, et al., Charlotte Lozier Inst., Am Reps. Series No. 20, *Overlooked Dangers of Mifepristone, the FDA's Reduced REMS, and Self-Managed Abortion Policies: Unwanted Abortions, Unnecessary Abortions, Unsafe Abortions* 9 (2021) ("Even after widespread use for over 20 years, there have still been no randomized trials investigating the mid- to longer-term complications associated with mifepristone-induced abortions. The FDA's politically motivated waiver of the normal safety research protocols has simply been extended without ever looking back.").

depression, anxiety, and reduced quality of life scores in social and mental health categories." *Id.*; *see*, *e.g.*, Louis Jacob et al., *Association Between Induced Abortion, Spontaneous Abortion, and Infertility Respectively and the Risk of Psychiatric Disorders in 57,770 Women Followed in Gynecological Practices in Germany*, 251 J. Affective Disorders 107, 111 (2019) (finding "a positive relationship between induced abortion . . . and psychiatric disorders in gynecological practices in Germany").

Thus, chemical abortions carry significant risks for women's health and safety. The FDA's deregulation in 2016 and 2021 has heightened these risks.

C. The FDA's Actions Have Endangered Patient Health and Safety.

The FDA removed multiple safeguards in 2016 and 2021 to the detriment of patient welfare. Again, discussed *supra* Section I.A, the FDA had "insufficient information to determine whether such drug is safe for use under such conditions." 21 U.S.C. § 355(d)(4). There is also evidence, including from the FDA's own drug label, that now "such drug is unsafe for use under such conditions." *Id*. at § 355(d)(2).

In 2016, the FDA eliminated the requirement that medical professionals conduct an in-person follow-up appointment for women after taking chemical abortion drugs. *All. for Hippocratic Med.*, 78 F. 4th at 225. This decision is in tension with the FDA's drug

label for mifepristone, which primarily relies upon in-person evaluation of the woman. The FDA directs that medical professionals may use a woman's medical history—which can be done via telemedicine—during a follow-up appointment to assess the woman's degree of bleeding as well as whether the chemical abortion ended the pregnancy. *Mifeprex Prescribing Information*, *supra*, at 4. Medical history has severe limitations in this context, however, because "prolonged or heavy bleeding is not proof of a complete abortion." *Id.* The label indicates that in-person "clinical examination, human Chorionic Gonadotropin (hCG) testing, or ultrasonographic scan" alternatively can assess the woman. *Id.*

Even though the FDA acknowledges that "Mifeprex may cause serious side effects," *id.* at 19, the agency nevertheless permitted non-physicians to prescribe the drugs beginning in 2016. *All. for Hippocratic Med.*, 78 F. 4th at 225. Yet, "[a]ncillary healthcare workers do not have the same level of training as physicians." Rsch. Comm., Am. Ass'n Pro-Life Obstetricians & Gynecologists, *State Restrictions on Abortion: Evidence-Based Guidance for Policymakers*, Comm. Op. No. 10, at 10 (updated 2022). Consequently, "[p]rovision of surgical procedures by health care providers who are not trained in recognizing or treating the complications that inevitably follow greatly increase the risk to women who undergo these procedures." *Id.*

The 2021 deregulation further increased risks to women. By allowing "no-test, mail-order abortions after a telemedicine visit, the FDA has abandoned its dual obligations to protect the public and vulnerable populations from harm and to comply with Federal law, including Federal requirements to protect patient safety . . . ."[4] In-person visits are necessary for chemical abortions as a matter of basic patient health and safety. The Mayo Clinic states that: "Medical abortion isn't an option if you . . . *[c]an't make follow-up visits to your provider* or don't have access to emergency care."[5] Medical institutions are in agreement about this, as "[a] medical abortion involves at least two visits to a doctor's office or clinic." *Medical Abortion*, Univ. of Cal. San Francisco Health, www.ucsfhealth.org/treatments/medical-abortion (last visited Feb. 1, 2024). Follow-up visits are critical to ensure that if a woman has retained fetal remains, she receives essential follow-up care.

But even before a chemical abortion, healthcare providers must confirm a woman is, in their determination, a medically appropriate candidate for chemical abortion. In most states, this consultation is with a physician. In a few states, it can be done by a

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[4] Letter from Cindy Hyde-Smith, Senator, U.S. Cong., et al., to Robert Califf, Comm'r, U.S. Food & Drug Admin. 5 (Jan. 26, 2023), https://www.hydesmith.senate.gov/sites/default/files/2023-01/012623%20Bicameral%20Letter%20to%20FDA%20re%20Abortion%20Drugs.pdf.

[5] *Medical Abortion*, Mayo Clinic (July 29, 2022), https://www.mayoclinic.org/tests-procedures/medical-abortion/about/pac-20394687 (emphasis in original).

midlevel provider, such as a nurse practitioner, certified nurse-midwife, or physician assistant. *E.g.*, Cal. Bus. & Prof. Code § 2253(b) (2022). A number of medical conditions make a woman ineligible to take chemical abortion drugs, including having a potentially dangerous ectopic pregnancy (a pregnancy outside of the uterus) or having an intrauterine device (IUD) in place. *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, *supra*. Chemical abortion cannot terminate an ectopic pregnancy and carries heightened risk to the woman's health later into pregnancy *Id*. The FDA label warns medical professionals to "[e]xclude [an ectopic pregnancy] before treatment." *Mifeprex Prescribing Information*, *supra*, at 1. Yet, a physician can only diagnose an ectopic pregnancy by blood tests and an ultrasound, which means a physician cannot determine via telemedicine whether a pregnancy is ectopic.[6]

Determining gestational age usually is done in person by ultrasound. Ultrasound is the most accurate method to establish or confirm gestational age in the first trimester. Comm. on Obstetric Practice, Am. Coll. of Obstetricians & Gynecologists et al., *Methods for Estimating the Due Date*, Comm. Op. No. 700, at 1 (reaffirmed 2022). Dating a pregnancy by using a woman's last menstrual period (LMP) is far less accurate. The American College of

[6] *Ectopic Pregnancy*, Mayo Clinic (Mar. 12, 2022), https://www.mayoclinic.org/diseases-conditions/ectopic-pregnancy/diagnosis-treatment/drc-20372093.

Obstetricians and Gynecologists (ACOG) indicates only one half of women accurately recall their LMP. *Id*. at 2. In one study, forty percent of women had more than a five-day discrepancy between their LMP dating and the ultrasound dating. *Id*. In this regard, LMP dating is not nearly as precise as an ultrasound. The FDA label indicates "pregnancy is dated from the first day of the last menstrual period," but medical professionals should "[a]ssess the pregnancy by ultrasonographic scan if the duration of pregnancy is uncertain or if ectopic pregnancy is suspected." *Mifeprex Prescribing Information*, *supra*, at 2. Accordingly, an accurate measurement of gestational age is required to show that a woman is even a candidate for a chemical abortion.

Without an in-person evaluation, abortion providers also cannot test for Rh negative blood type. The FDA label indicates, "[t]he use of MIFEPREX is assumed to require the same preventive measures as those taken prior to and during surgical abortion to prevent rhesus immunization." *Id*. at 6. During pregnancy, if a woman has Rh negative blood while her fetus is Rh positive, the woman's body may produce antibodies after exposure to fetal red blood cells. *Rh Factor Blood Test*, Mayo Clinic (July 29, 2022), https://www.mayoclinic.org/tests-procedures/rh-factor/about/pac-20394960. Abortion can cause maternal exposure to fetal blood, even in the first trimester. *Id*. Therefore, if indicated, a healthcare provider must give a woman with Rh negative blood an Rh immuneglobulin injection. Without the injection, antibodies can damage future

pregnancies by creating life-threatening anemia in fetal red blood cells. *Id.* ACOG describes that "Rh testing is recommended in patients with unknown Rh status before medication abortion, and Rh D immunoglobulin should be administered if indicated." Comm. On Practice Bulletins—Gynecology and the Soc'y of Family Planning, Am. Coll. of Obstetricians & Gynecologists, *Medication Abortion Up to 70 Days of Gestation*, Comm. Op. 225, at 40 (reaffirmed 2023). Rh negative blood typing is thus a medically necessary test, but it cannot occur during chemical abortion consultations that are done entirely via telemedicine.

A woman seeking an abortion may be facing intimate partner violence (IPV). There are "[h]igh rates of physical, sexual, and emotional IPV . . . among women seeking a[n abortion]." Megan Hall et al., *Associations Between Intimate Partner Violence and Termination of Pregnancy: A Systematic Review and Meta-Analysis*, PLOS Med., Jan. 7, 2014, at 1, 15. For women seeking abortion, the prevalence of IPV is nearly three times greater than women continuing a pregnancy. Comm. on Health Care for Underserved Women, Am. Coll. of Obstetricians & Gynecologists, *Reproductive and Sexual Coercion*, Comm. Op. No. 554, at 2 (reaffirmed 2022). Post-abortive IPV victims also have a "significant association" with "psychosocial problems including depression . . . , suicidal ideation . . . , stress . . . , and disturbing thoughts." Hall, *supra*, at 11.

Medical professionals must "[s]creen for IPV in a private and safe setting with the woman alone and

not with her partner, friends, family, or caregiver." Comm. on Health Care for Underserved Women, Am. Coll. of Obstetricians & Gynecologists, *Intimate Partner Violence*, Comm. Op. No. 518, at 3 (reaffirmed 2022). Yet, telemedicine cannot ensure that a coercive partner, friend, family member, or caregiver is not in the room with a woman seeking a chemical abortion. In a telehealth setting, ACOG recommends healthcare providers screen patients multiple times because patients may not be able to disclose abuse each time they are screened. *COVID-19 FAQs for Obstetricians-Gynecologists, Obstetrics*, Am. Coll. of Obstetricians & Gynecologists (rev. July 1, 2021), https://www.acog.org/clinical-information/physician-faqs/covid-19-faqs-for-ob-gyns-obstetrics; *see also Intimate Partner Violence*, *supra*, at 3 (noting IPV screening should occur periodically and "at various times . . . because some women do not disclose abuse the first time they are asked"). In other words, domestic violence screening by telehealth "may not allow individuals the privacy or safety needed to disclose abuse." *Id*. Thus, telehealth ineffectively screens a woman seeking chemical abortions for domestic violence or coercion. If she changes her mind, no medical professional is there to help her. She is left alone to care for her physiological and psychological health, as well as her safety if complications or IPV arise. Thus, the FDA's deregulation of mifepristone has increased the risks to patient health and safety.

In sum, the FDA failed to follow the FDCA's patient safety requirements when it removed patient

safeguards in 2016 and 2021, which violate the APA, and are to the detriment of the health and safety of women and girls seeking chemical abortion drugs.

II. THE FDA HAS PERMITTED MAIL-ORDER CHEMICAL ABORTION DRUGS IN VIOLATION OF FEDERAL LAW.

The FDA's 2021 action sanctions the shipment of abortion drugs, including through mail-order pharmacies, which violates longstanding federal laws. Congress has barred the abortion industry from using the United States Postal Service and common carriers to mail abortion-inducing drugs, including the chemical abortion regimen of mifepristone and misoprostol. *See* 18 U.S.C. § 1461. Congress has separately prohibited the abortion industry from shipping abortion-inducing drugs through common carriers. *See* 18 U.S.C. § 1462.

These provisions have been federal policy for more than a century. *See* Act of Mar. 3, 1873, ch. 258, 17 Stat. 598 (codified as amended at 18 U.S.C. § 1461) Act of Feb. 8, 1897, ch. 172, 29 Stat. 512 (codified as amended at 18 U.S.C. § 1462).[7] Congress has never removed the prohibition on mailing chemical abortion

[7] Federal statutes are overwhelmingly pro-life, and include abortion funding restrictions, *e.g.,* 42 U.S.C. § 300a-6, conscience protections, *e.g.*, 42 U.S.C. § 300a-7, the Born-Alive Infants Protection Act, 1 U.S.C. § 8, and Partial-Birth Abortion Ban Act, 18 U.S.C. § 1531. 18 U.S.C. §§ 1461–1462 is consistent with other federal pro-life policies by likewise limiting the harms of abortion.

drugs.[8] Congress considered and rejected a legislative proposal that would have amended 18 U.S.C. §§ 1461–1462 to apply only to "illegal abortions." *See* H.R. Rep. No. 95-29, pt. 3, at 42 (1978).

Congress' clear intent is for all federal agencies, including the FDA, to comply with 18 U.S.C. §§ 1461–1462. This includes any "officer, agent, or employee of the United States." 18 U.S.C. § 552.

The FDA blatantly violated the prohibition on mailing chemical abortion drugs by permitting mail-order chemical abortions.[9] This action comes at the

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[8] *E.g.*, Act of Feb. 8, 1905, ch. 550, 33 Stat. 705 (expanding the law to bar the importation and exportation of abortion drugs), An Act to Revise, Codify, and Enact into Positive Law, Title 18 of the United States Code, entitled "Crimes and Criminal Procedure," Pub. L. No. 80-772, 62 Stat. 683, 768 (1948) (recodifying the provisions now contained in 18 U.S.C. §§ 1461–1462); An Act to Amend the Tariff Act of 1930 and the United States Code to Remove the Prohibitions Against Importing, Transporting, and Mailing in the United States Mails Articles for Preventing Conception, Pub. L. No. 91-662, 84 Stat. 1973 (1971) (removing contraceptives from the scope of 18 U.S.C. §§ 1461–1462); Violent Crime Control and Law Enforcement Act of 1994, Pub. L. 103–322, tit. XXXIII, § 330,016(1)(K), (L), 108 Stat. 1796, 2147 (1994); Telecommunications Act of 1996, Pub. L. No. 104-104, tit. V, subtit. A, § 507(a), 110 Stat. 56, 137 (1996) (amending 18 U.S.C. § 1462 to bar the abortion industry from using an "interactive computer service" for the interstate carriage of abortion drugs).

[9] In response to the Department of Justice Office of Legal Counsel's memorandum of December 23, 2022 contending 18 U.S.C. §§ 1461–1462 does not prohibit the mailing of the chemical abortion drugs mifepristone or misoprostol "where the sender lacks the intent that the recipient of the drugs will use

expense of women's health and safety, discussed *supra* Section I.C. In 2021, the FDA "authorize[d] the dispensing of mifepristone 'through the mail . . . or through a mail-order pharmacy,'" even though that "is precisely what [18 U.S.C. §§ 1461–1462] prohibits." *All. for Hippocratic Med.*, 78 F. 4th at 268 (Ho, J., concurring) (citation omitted) (second alteration in original). "The FDA's 2023 Risk Evaluation and Mitigation Strategy modification doubles down on this violation by permanently eliminating the in-person dispensing requirement." *Id*. Accordingly, the FDA's "2021 revisions violate [18 U.S.C. §§ 1461–1462] . . . and are 'not in accordance with law'" for that reason as well." *Id*. at 267 (citing 5 U.S.C. § 706(2)(A)).

In sum, "[i]n loosening mifepristone's safety restrictions, FDA failed to address several important concerns about whether the drug would be safe for the women who use it," *All. for Hippocratic Med.*, 78 F. 4th at 256, and blatantly ignored federal restrictions on the mailing and interstate shipment of abortion-inducing drugs. The FDA's 2016 and 2021 actions subverted patient safeguards when it violated the

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them unlawfully," Members of Congress wrote to Attorney General Merrick Garland, reminding him that the "neither Congress nor the courts have articulated such an interpretation of the law that radically departs from the plain text and clear meaning of the law." Letter from James Lankford, Senator, U.S. Cong., et al., to Merrick B. Garland, Att'y Gen., U.S. Dep't of Just. 1 (Jan. 25, 2023), https://www.lankford.senate.gov/imo/media/doc/dojletterabortionmail.pdf.

requirements of the APA, FDCA, and 18 U.S.C. §§ 1461–1462.

CONCLUSION

The FDA's unlawful deregulation of chemical abortion drugs has endangered patient health and safety. For the reasons set forth above, *Amici* urge this Court to affirm the Section 705 stay of the FDA's 2016 and 2021 unlawful actions.

Respectfully submitted,

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February 29, 2023

APPENDIX

APPENDIX TABLE OF CONTENTS

LIST OF *AMICI CURIAE*

U.S. Senate

Lead Senator: Cindy Hyde-Smith (MS)

U.S. House of Representatives

Lead Representative: August Pfluger (TX–11)