Nos. 23-235 & 23-236

IN THE

Supreme Court of the United States

U.S. FOOD & 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 OVER 300 REPRODUCTIVE HEALTH RESEARCHERS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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January 30, 2024

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D.C. 20002

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INTEREST OF THE *AMICI CURIAE*[1]

Amici curiae are leading reproductive health researchers in the United States and worldwide. *Amici* are trained and experienced in conducting or evaluating clinical and social science studies on reproductive health issues, including studies on the safety and effectiveness of mifepristone. *Amici* share a significant interest in evidence-based reproductive health care, and submit this brief to explain the ample scientific evidence of mifepristone's safety and effectiveness supporting the Food and Drug Administration's 2016 and 2021 decisions.

SUMMARY OF ARGUMENT

This Court should not allow the politics of abortion to obscure the clear, abundant, and plainly sufficient scientific record supporting FDA's decision-making in this case. In approving certain modifications to mifepristone's Risk Evaluation and Mitigation Strategy ("REMS") and labeling in 2016 and 2021, FDA reviewed and relied on extensive scientific evidence conclusively showing the safety and effectiveness of the changes.

In 2016, FDA modified the mifepristone REMS to permit healthcare providers with prescriptive authority under state law (such as nurse practitioners and physician assistants) to become certified prescribers of mifepristone, and updated the dosing regimen, gestational limit, and number of required in-clinic visits included in mifepristone's labeling. In evaluating the

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

safety and effectiveness of these changes, FDA reviewed 58 scientific studies, which together analyzed tens of thousands of patient experiences. These studies were conducted by qualified experts and adhered to rigorous standards of reliability and validity, as demonstrated by their selection for publication in reputable scientific journals, subject to the rigorous academic peer-review process. The record makes clear that FDA extensively studied each individual change and that, contrary to the Fifth Circuit's conclusion, FDA also analyzed the individual changes as "interrelated," including reviewing many studies containing all or almost all the changes in combination. Without exception, these studies demonstrated that the modifications to the REMS and the labeling continued to ensure that mifepristone remained extremely safe—with rates of serious adverse events generally far below 1.0%—and extremely effective—generally resulting in complete pregnancy termination without procedural intervention in over 96% of cases. These rates are comparable or superior to those observed in studies assessing safety and effectiveness of medication abortion care under the prior, more restrictive REMS and labeling.

FDA's decision to eliminate the in-person dispensing requirement from the REMS in 2021, formalized in 2023, was also supported by ample scientific evidence. FDA's multiple analyses of this REMS requirement during 2021 encompassed 25 high quality scientific studies, which together covered more than 50,000 patient experiences. These studies confirmed conclusively that mifepristone remains extremely safe and effective without the requirement that the medication be dispensed only at a hospital, clinic, or medical office. Other studies considered by FDA also demonstrated that the in-person dispensing requirement reduced access to mifepristone. Given this evidence, FDA

properly determined that the in-person dispensing requirement was inconsistent with the statutory requirements for maintaining REMS elements to assure safe use, and appropriately removed it. *See* 21 U.S.C. § 355-1(f)(2) (elements to assure safe use within a REMS must be "commensurate with [a] specific serious risk listed in the labeling of the drug," and cannot be "unduly burdensome on patient access to the drug, considering in particular . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)").

It is clear that the evidentiary support for FDA's 2016 and 2021 decisions far exceeded the statutory requirements. *See* 21 U.S.C. 355(d) ("[D]ata from *one* adequate and well-controlled clinical investigation and confirmatory evidence" may be sufficient) (emphasis added); 21 U.S.C. § 355-1(g) (modification of a REMS need only be supported by an assessment and an "adequate rationale"). Pursuant to the statutory requirements, FDA regularly approves drugs supported by only one clinical study.[2] In this case, the record supporting the 2016 and 2021 changes to mifepristone's REMS and labeling demonstrates that FDA not only met its statutory requirements, but also went well beyond them.

Amici submit this brief to explain the vast scientific evidence supporting each component and the totality of FDA's 2016 and 2021 Decisions. The studies leave no doubt as to the safety and effectiveness of mifepristone's modified REMS and labeling. Consistent with

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[2] *See* Kaplan et al., *Review of evidence supporting 2022 US Food and Drug Administration drug approvals*, 6 JAMA NETWORK OPEN e2327650 (2023) (finding that 65% percent of approved novel drugs in 2022 were supported by one clinical study).

this overwhelming evidence, this Court should reverse the Fifth Circuit's decision.

ARGUMENT

I. FDA's 2016 Decision, Modifying Mifepristone's REMS and Labeling, Was Supported by Ample Scientific Evidence.

Extensive data from many rigorous scientific studies supported FDA's 2016 Decision to modify its regulation of mifepristone. Indeed, FDA reviewed robust evidence far exceeding the statutory requirements for modifications of the REMS[3] and for changes to a label's conditions of use.[4] The data clearly demonstrated that medication abortion using mifepristone and misoprostol is both extremely effective—defined as resulting in a complete abortion without need for procedural

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[3] FDA has wide discretion in determining the information needed to support modifying a REMS; modifications to a REMS need only be supported by "adequate rationale." 21 U.S.C. § 355-1(g)(4)(a).

[4] A supplemental application seeking changes to conditions of use must be supported by sufficient evidence of safety and substantial evidence of effectiveness. 21 U.S.C. § 505(b); 21 U.S.C. 355(d). "Substantial evidence" is defined as "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts 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 labeling or proposed labeling thereof." 21 U.S.C. 355(d). "[D]ata from *one* adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) . . . [may] constitute substantial evidence." *Id.* (emphasis added). Pursuant to the statutory requirements, FDA regularly approves drugs supported by only one clinical study. *See supra* note 2.

intervention—and extremely safe—defined as the absence of serious adverse events such as hospital admission, major surgery, or blood transfusion.

To be clear, the Fifth Circuit did not conclude—and could not conclude, consistent with the record—that there was insufficient evidence supporting each individual 2016 change. *See* App. 53a-56a.[5] Rather, the Fifth Circuit concluded that the 2016 Decision was likely arbitrary and capricious because FDA failed to evaluate the individual changes in combination. *Id.* The record plainly refutes that conclusion. As set forth below, FDA reviewed and relied on numerous studies conclusively demonstrating that the changes were safe and effective both individually and in combination.[6]

A. Extensive Scientific Evidence Supported Permitting Prescribing Healthcare Providers to Be Certified Prescribers of Mifepristone.

The Fifth Circuit did not conclude, and could not conclude based on the record, that there was insufficient evidence of the safety and efficacy supporting FDA's 2016 determination to permit healthcare providers with prescriptive authority under state law to become certified prescribers of mifepristone. *See* App. 53a-56a. In evaluating whether these providers could safely and effectively prescribe and dispense mifepristone,

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[5] "App." refers to the Appendix to the Petition for a Writ of Certiorari filed by Petitioners U.S. Food and Drug Administration, et al.

[6] Although Sections I.A-D focus on the evidence supporting each individual 2016 change, many of the studies discussed in those Sections contained more than one relevant change. Section I.E discusses the many studies evaluating all or almost all the 2016 changes in combination.

FDA relied primarily on three randomized controlled trials with a combined 3,200 participants and one cohort study with 596 participants. J.A. 302, 461-62, 495-98. Those studies found no differences in effectiveness or safety between patients who received mifepristone from physicians compared to those who were prescribed and dispensed mifepristone by other healthcare professionals. J.A. 316.[7]

Two FDA-reviewed randomized controlled trials designed to test for equivalence between nurses and physicians both found that nurses could provide equivalent care. The first evaluated outcomes of 938 patients and found equivalent safety and efficacy between nurse-midwives and physicians.[8] Indeed, the nurse-midwife group actually demonstrated *higher* efficacy at 99.0% vs. 97.4% among the physician group.[9] The second, with 1,077 participants, also found that nurses and auxiliary nurse-midwives provided medication abortion with statistically equivalent efficacy to physicians, reporting complete abortion rates of 97.3% compared to 96.1% for physicians.[10]

Another FDA-reviewed randomized controlled trial designed to test for non-inferiority between nurses and physicians included 884 participants and determined

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[7] "J.A." refers to the Joint Appendix filed by Petitioners U.S. Food and Drug Administration, et al. on January 23, 2024.

[8] Kopp Kallner et al., *The efficacy, safety and acceptability of medical termination of pregnancy provided by standard care by doctors or by nurse-midwives: a randomized controlled equivalence trial*, 122 BJOG 510 (2015).

[9] *Id.*

[10] Warriner et al., *Can midlevel health-care providers administer early medical abortion as safely and effectively as doctors? A randomised controlled equivalence trial in Nepal*, 377 THE LANCET 1155 (2011).

that nurse provision of medication abortion was not inferior to physician provision, with complete abortion rates of 97.9% in the nurse group compared to 98.4% in the physician group.[11] Only one serious adverse event (bleeding) was reported in the trial, by a patient who had been seen by a physician.[12]

Further research has continued to confirm that healthcare providers with prescriptive authority can safely and effectively provide medication abortion care. For example, a 2018 study of 605 patients found that nurse-midwives could provide effective medication abortion care at both health facilities (97.4% efficacy) and pharmacies (98.7% efficacy), without any serious adverse events.[13]

There was ample evidence supporting the REMS modification, and evidence gathered since the 2016 Decision has only affirmed the safety and effectiveness of provision by these healthcare providers.

B. Extensive Scientific Evidence Supported the Safety and Effectiveness of the Amended Dosing Regimen Indicated on the Label.

The Fifth Circuit did not conclude, and could not conclude based on the record, that there was insufficient evidence supporting the safety and effectiveness of the amended dosing regimen indicated on the

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[11] Diaz Olavarrieta et al., *Nurse versus physician-provision of early medical abortion in Mexico: a randomized controlled non-inferiority trial*, 93 BULL. WORLD HEALTH ORG. 249 (2015).

[12] *Id.*

[13] Rocca et al., *Effectiveness and safety of early medication abortion provided in pharmacies by auxiliary nurse-midwives: A non-inferiority study in Nepal*, PLOS ONE (2018).

label.[14] *See* App. 53a-56a. Indeed, FDA reviewed and relied upon at least 24 studies conclusively demonstrating the safety and effectiveness of the amended dosing regimen, which decreased the oral dose of mifepristone from 600 mg to 200 mg, changed the misoprostol dose from 400 mcg administered orally 48 hours after administration of mifepristone to 800 mcg administered buccally 24-48 hours after administration of mifepristone, and allowed for a repeat dose of misoprostol to ensure completion. J.A. 299-301, 442-50, 459-61, 478-79, 481-82.

FDA relied upon a systematic review of clinical outcomes from twenty studies, including a total of 33,846 individuals, using 200 mg oral mifepristone followed by 800 mcg buccal misoprostol.[15] Of the twenty studies using the amended dose and routes of administration, fifteen studies used a 24-48 hour dosing interval, and four studies allowed for repeat dosing of misoprostol to ensure completion.[16] The review found that the effectiveness of the amended dosing regimen was 96.7%, *notably higher* than the 92.1% efficacy rate of the regimen FDA approved in 2000.[17] The review also demonstrated the overwhelming safety of the dosing regimen: across the 20 studies,

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[14] As relevant here, the "dosing regimen" consists of the "dose" (the quantity of medication), the "route of administration" (how the medication is taken), and the "dosing interval" (the time between taking each medication).

[15] Chen et al., *Mifepristone with buccal misoprostol for medical abortion, a systematic review*, 126 OBSTET. GYNECOL. 12 (2015).

[16] *Id.*

[17] *Id.*

serious adverse events were extremely rare, ranging between 0.01%-0.9%.[18]

In addition to the systematic review, FDA evaluated many other studies providing conclusive evidence that the amended dosing regimen was safe and effective. In one such study, 1,349 individuals used the amended dosing regimen resulting in a 98.3% effectiveness rate.[19] Another FDA-reviewed study demonstrated through a randomized controlled trial that buccal administration of 800 mcg misoprostol after 200 mg mifepristone was 96.2% effective.[20]

Other FDA-reviewed studies similarly showed safety and effectiveness of the amended dosing regimen, and a higher effectiveness rate than the dosing regimen included in the FDA labeling at the time. One study showed that a dosing regimen of 200 mg oral mifepristone followed by either 400 mcg or 800 mcg buccal misoprostol resulted in 96.4% effectiveness.[21] Another study using the amended dosing regimen found 98.7% effectiveness rates for site-to-site telemedicine patients[22] and 96.9% for face-to-face patients, with low rates of serious adverse events among both groups of patients,

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[18] *Id.*

[19] Fjerstad et al., *Effectiveness of medical abortion with mifepristone and buccal misoprostol though 59 gestational days*, 80 CONTRACEPTION 282 (2009).

[20] Winikoff et al*., Two distinct oral routes of misoprostol in mifepristone medical abortion*, 112 OBSTET. GYNECOL. 1303 (2008).

[21] Chong et al., *A randomized controlled trial of different buccal misoprostol doses in mifepristone medical abortion,* 86 CONTRACEPTION 251 (2012).

[22] This study used a site-to-site telemedicine model, in which patients visit a health center to meet remotely with a clinician located in another health center.

including zero deaths and zero hospitalizations out of 578 participants.[23]

Incomplete abortions are extremely rare when using the amended dosing regimen, and FDA's decision to allow for an additional dose of misoprostol in cases of incomplete abortion was also well supported. In making this decision, FDA relied on several studies totaling over 4,000 patients; of these, only 3.4% had an incomplete abortion and took a second dose, which resulted in complete abortion in 90% of those cases. J.A. 460.[24] In other words, among the small portion of patients who experience incomplete abortion, the overwhelming majority can avert a procedural intervention and complete their termination by taking an additional dose of misoprostol. Indeed, FDA acknowledged in its review that offering this additional dose was already "standard protocol in many US clinics," underscoring that the change brought the label into alignment with existing, evidence-based clinical practice. J.A. 461.

In sum, the evidence of the safety and effectiveness of the amended dosing regimen indicated on the label far exceeded the necessary showing to support a change to the conditions of use.

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[23] Grossman et al., *Effectiveness and acceptability of medical abortion provided through telemedicine*, 118 OBSTET. GYNECOL. 296 (2011).

[24] *See also* Gallo et al., *A systematic review of more than one dose of misoprostol after mifepristone for abortion up to 10 weeks of gestation*, 74 CONTRACEPTION 36 (2006) (systematic review of studies of additional dose of misoprostol, including three randomized controlled trials finding no differences in effectiveness and no serious adverse events).

C. Extensive Scientific Evidence Supported the Safety and Effectiveness of Increasing the Gestational Limit Indicated on the Label.

The Fifth Circuit did not, and could not based on the record, conclude that there was insufficient evidence supporting the safety and efficacy of increasing the gestational limit listed in the mifepristone labeling from 49 to 70 days. *See* App. 53a-56a. FDA reviewed a number of studies providing strong support for extending the gestational limit past 49 days, including studies evaluating medication abortion safety and efficacy at multiple gestational durations up through 70 days. J.A. 299, 450-56, 478-79. Of critical importance were several primary studies and the above-discussed systematic review, which together evaluated over 30,000 patients using the exact proposed dosing regimen through 70 days' gestation. Based on this extensive evidence, FDA concluded that mifepristone's efficacy at 50-70 days was comparable to that of the initial 2000 approval for up to 49 days gestation. Furthermore, FDA found "no association between adverse outcomes and increasing gestational age." J.A. 310.

A study using data from 629 patients across the United States specifically compared outcomes of medication abortion patients between 57-63 days gestation to those at 64-70 days and found that rates of complete abortion were statistically equivalent at both gestational ranges.[25] The study also found no significant difference in serious adverse events based on gestation.[26]

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[25] Winikoff et al., *Extending outpatient medical abortion services through 70 days of gestational age*, 120 OBSTET. GYNECOL. 1070 (2012).

[26] *Id*.

Another study reviewed by FDA also found equivalent efficacy at 64-70 days compared to earlier gestations, with data from 307 individuals using the 2016 dosing regimen offered up to 70 days gestation, which was effective in 97.7% of cases.[27]

FDA also evaluated a study including 960 patients who received medication abortion up to 70 days gestation, finding high effectiveness at all gestational ranges, with an average of 93.3%, which is within the range of other studies with similar protocols.[28] Finally, the systematic review, which evaluated the results of 20 studies for a combined total of 33,846 individuals, found high effectiveness for medication abortion through 64-70 days gestation (93.1%).[29]

The evidence before FDA in 2016 was more than sufficient to support extending the gestational limit indicated on the label, through 70 days.

D. Extensive Scientific Evidence Supported the Safety and Effectiveness of Reducing the Number of In-Person Clinical Visits Indicated on the Label.

The Fifth Circuit did not conclude, and could not conclude based on the record, that there was insufficient evidence supporting FDA's determination to reduce

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[27] Boersma et al., *Mifepristone followed by home administration of buccal misoprostol for medical abortion up to 70 days of amenorrhoea in a general practice in Curaçao*, 16 EUR. J. CONTRACEPT. REPROD. HEALTH CARE 61 (2011).

[28] Sanhueza Smith et al., *Safety, efficacy and acceptability of outpatient mifepristone-misoprostol medical abortion through 70 days since last menstrual period in public sector facilities in Mexico City*, 22 REPROD. HEALTH MATTERS 75 (2015).

[29] Chen et al., *supra* note 15.

the number of in-person clinical visits listed in the mifepristone labeling. *See* App. 53a-56a. Prior to the 2016 changes, the approved dosing regimen involved three in-person appointments: (1) administration of mifepristone on the first day, (2) administration of misoprostol on the third day, and (3) follow-up on the fourteenth day to confirm pregnancy termination. The evidence before FDA in 2016 strongly supported reducing the number of in-person clinical visits indicated in the labeling, given the well-documented safety of patients taking misoprostol at home and following up with their provider remotely.[30] J.A. 300-302, 456-59, 462, 479-85.

In evaluating whether to retain the language indicating that misoprostol be administered in clinic, FDA relied on nearly a dozen studies involving large numbers of participants, all of which showed that it is extremely effective and extremely safe for people to complete the two-drug protocol at home, with "exceedingly low" rates of serious adverse events. J.A. 308. This evidence included a systematic review which analyzed 87 studies covering over 45,000 patients using a range of mifepristone and misoprostol treatment regimens, about half of which involved home administration of misoprostol.[31] Efficacy of the regimens was found to be similar whether or not misoprostol was taken in clinic and there was "no

[30] For discussion of the evidence before FDA in 2021 to remove the first in-person clinical visit, see *infra* Section II.

[31] Raymond et al., *First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review*, 87 CONTRACEPTION 26 (2013).

evidence" that allowing home administration of misoprostol increased rates of adverse events.[32]

FDA also considered individual studies, including four U.S.-based studies totaling over 14,700 patients and seven international studies totaling over 16,000 patients. These studies showed that medication abortion with misoprostol administered at home is highly effective, with rates of complete abortion ranging between 91.9-97.7%. J.A. 458. In particular, the largest U.S.-based study collected data on 13,373 patients over five years, using the dosing regimen approved in 2016 with misoprostol taken at home.[33] The regimen was effective in 97.7% of cases; only six people over the entire study period developed a serious adverse event requiring hospitalization, with incidence of hospitalization less than or equal to 0.18% at all gestations,[34] which is consistent with research showing similarly low prevalence of adverse events among patients who take misoprostol at home and in clinic.[35]

Furthermore, the evidence available to FDA in 2016 supported home administration not only of misoprostol, but also of mifepristone. In one study, 301 patients were given the choice to take mifepristone at home or in their physician's office—46% chose to take mifepris-

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[32] *Id.* at 32.

[33] Gatter et al., *Efficacy and safety of medical abortion using mifepristone and buccal misoprostol though 63 days*, 91 CONTRACEPTION 269 (2015).

[34] *Id.*

[35] *See, e.g.*, Ngo et al., C*omparative effectiveness, safety and acceptability of medical abortion at home and in a clinic: a systematic review*, 89 BULL. WORLD HEALTH ORG. 360 (2011).

tone at home, and all took misoprostol at home.[36] The authors found no differences in effectiveness or serious adverse events between groups.[37]

Ample evidence also supported flexibility with regards to timing and method of follow-up assessment. In particular, FDA relied on the 2013 systematic review of over 45,000 medication abortions, which found no association between efficacy and timing of follow-up.[38] FDA also relied on a systematic review of studies examining alternatives to in-person ultrasound follow-up, which identified eight studies that together enrolled almost 2,400 participants and evaluated a variety of follow-up methods, including remote methods such as phone screening, standardized questionnaires, and at-home pregnancy tests.[39] The studies analyzed in the review identified remote methods that were suitable alternatives to ultrasound follow-up (serum human chorionic gonadotropin (hCG) measurement, urine pregnancy test plus standardized self-assessment, and standardized telephone consultation with a provider); these methods identified over 90% of patients with continuing pregnancy and produced fewer than 1% false positives.[40] Overall, FDA noted that the proportion of patients unable to be reached for follow-up in these studies "do[es] not appear to exceed those associated with a planned in-clinic follow-up." J.A.

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[36] Swica et al., *Acceptability of home use of mifepristone for medical abortion*, 88 CONTRACEPTION 122 (2013).

[37] *Id.*

[38] Raymond, *supra* note 31.

[39] Grossman et al., *Alternatives to ultrasound for follow-up after medication abortion: a systematic review*, 83 CONTRACEPTION 504 (2011).

[40] *Id.*

484-85. In addition to these systematic reviews, FDA also considered multiple individual studies permitting remote follow-up; for example, one study of over 1700 patients who chose self-assessment follow-up, finding no more delays in care than would be expected for in-clinic follow-up.[41]

These extensive data, demonstrating the safety and efficacy of home administration of misoprostol and flexibility in follow-up assessments, were more than sufficient to support FDA's labeling change.

E. FDA's Judgment that the Individual Changes in 2016 Were Collectively Safe and Effective Was Supported by a Robust Record of Scientific Evidence.

Despite the vast data supporting each individual change, the Fifth Circuit held that FDA's 2016 decision was likely arbitrary and capricious because FDA failed to consider the effect of those changes "as a whole." App. 53a. Yet, the record makes clear that FDA relied on many studies evaluating combined aspects of the 2016 changes and analyzed the individual changes as "interrelated." J.A. 298 (reasoning that "in some cases data from a given study were relied on to provide evidence to support multiple changes"); J.A. 299, 446-49, 461.

For example, FDA reviewed and relied upon a randomized controlled trial with over 800 participants which supported the safety and effectiveness of provision by healthcare providers with prescriptive authority and mirrored the other aspects of the 2016 changes:

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[41] Cameron et al. *Can women determine the success of early medical termination of pregnancy themselves?* 91 CONTRACEPTION 6 (2015).

nurses provided the medication abortion, and participants had pregnancies of up to 70 days, used a dosing regimen of 200 mg oral mifepristone and 800 mcg buccal misoprostol with an additional misoprostol dose if needed, and administered the misoprostol at home 24 hours after taking the mifepristone.[42] These conditions, in combination, resulted in no serious adverse events and a 97.9% efficacy rate, which is higher than the 92.1% efficacy rate of the U.S. trial relied upon for FDA's approval of the regimen in 2000.[43]

Additionally, FDA reviewed and relied upon several large studies that closely matched the 2016 label changes by demonstrating the safety and effectiveness of at-home administration of misoprostol through 70 days, while also utilizing the same dosing regimen as the 2016 changes (200 mg oral mifepristone and 800 mcg misoprostol administered buccally 24-48 hours later, with an additional dose of misoprostol if needed). One such study found 92.8%-93.5% effectiveness and extremely rare occurrence of serious adverse events (between 0.41% and 0.69%).[44] Another such study found 93.3% effectiveness among 960 individuals using the amended dosing regimen, with at-home administration of misoprostol, through 70 days.[45]

FDA also considered studies showing the safety and effectiveness of provision by healthcare providers with prescriptive authority using the exact amended dosing regimen included in the updated labeling. In one such study of 938 individuals using 200 mg mifepristone and 800 mcg misoprostol and the option of at-home

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[42] Diaz Olavarrieta, *supra* note 11.

[43] *Id.*; J.A. 225.

[44] Winikoff, *supra* note 25.

[45] Sanhueza Smith, *supra* note 28.

misoprostol administration, 99% of patients treated by nurse-midwives had complete abortions and 95.8% did not need any unscheduled treatment—these numbers were high both as an absolute matter and as relative to physician prescription (97.4% effectiveness and 93.5% without need for additional treatment).[46] Moreover, many of the studies FDA considered in evaluating the amended dosing regimen also involved the provision of mifepristone up to 70 days.[47] As FDA observed in its review, the 2016 changes brought the regimen in line with World Health Organization guidelines. J.A. 445-46.

The foregoing evidence clearly demonstrates that the record before FDA in 2016 was more than sufficient to conclude that the proposed changes would be safe and effective in combination. Evidence gathered contemporaneously and since has only further confirmed that conclusion. Respondents assert that the 2016 changes created less safe conditions resulting in more required follow-up care, when in fact the opposite is true.

In *all* areas of medicine, "off-label" use of medications to reflect evolutions in evidence-based practice is permissible, common, and necessary to ensure that clinical care is not undermined by scientifically outdated labeling. Thus, even before FDA updated the mifepristone

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[46] Kopp Kallner, *supra* note 8; *see also* Puri et al., *The role of auxiliary nurse-midwives and community health volunteers in expanding access to medical abortion in rural Nepal*, 22 REPROD. HEALTH MATTERS 94 (2015) (study of nurse-midwife provision of the same dosing regimen of 200 mg mifepristone and 800 mcg misoprostol, with 82.3% self-administering misoprostol at home, and no reported serious adverse events).

[47] *See, e.g.,* Chen, *supra* note 15 (review summarizing clinical outcomes from 20 studies, including a total of 33,846 individuals, finding high effectiveness rates (96.7%) and extremely low rates of serious adverse events (0.01-0.9%).

labeling, prescribers were providing evidence-based care consistent with the studies described above—FDA's 2016 updates brought the labeling in line with that evidence-based clinical practice. But in 2011, Ohio passed a law mandating fidelity with the outdated conditions of use listed in the 2000 mifepristone labeling. Researchers then examined the medical records of 2,783 patients who obtained medication abortion before and after the law took effect.[48] The studied protocol from the period *before* the Ohio law took effect was very similar to the updated regimen FDA would adopt in 2016 and included 200 mg mifepristone and 800 mcg of misoprostol, with misoprostol allowed to be taken at home, flexibility in timing of follow-up (5-14 days), and a gestational limit beyond 49 days (63 days).[49] The research showed that this updated protocol was safer and more effective than the conditions of use in the original 2000 label that were still in effect when Ohio enacted this law. After the law mandating reversion to the outdated 2000 regimen, the proportion of patients requiring at least one additional clinical intervention increased from 4.9% to 14.3%; in other words, the odds of needing an additional intervention were three times higher under the pre-2016 regime.[50] The rate of adverse events (defined in this study as acute hemorrhage, infection, continuing pregnancy or incomplete abortion) increased from 2% to 5%.[51] In short, the pre-2016 labeling Respondents prefer would recommend a protocol that is actually *less* safe and would require

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[48] Upadhyay et al., *Comparison of outcomes before and after Ohio's law mandating use of the FDA-approved protocol for medication abortion: a retrospective cohort study.* PLOS MED. (2016).

[49] *Id.*

[50] *Id.*

[51] *Id.*

more clinical follow-up care—exactly what Respondents profess to wish to avoid.

Additional studies conducted after the 2016 decision contained *all* of the changes made in 2016 and further support the safety and effectiveness of the changes in combination. For example, a 2021 study of 110 patients using the same dosing regimen, a 70-day gestational limit, provision by nurse practitioners, at-home administration of misoprostol (and mifepristone), and remote follow-up resulted in a 95% effectiveness rate with no serious adverse events.[52]

In sum, the record clearly shows that FDA *did* consider many studies examining the effect of multiple proposed modifications prior to its 2016 decision, even though as the Fifth Circuit acknowledged, "FDA is not required to conduct a study that perfectly mirrors the conditions under which the drug will be used." App. 53a-54a. Indeed, FDA routinely approves drugs with conditions of use that differ from clinical trial protocols, as many clinical trial designs are more restrictive than recommended in post-approval clinical use, with additional caution exercised until the safety and efficacy of the product is demonstrated. In addition to the evidence affirmatively showing the changes were safe and effective in combination, there was also no evidence—at the time of the 2016 decision or since—suggesting that combining the proposed changes would lead to unsafe or ineffective outcomes.

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[52] Upadhyay et al., *Safety and efficacy of telehealth medication abortion in the US during the COVID-19 pandemic*, 4 JAMA NETWORK OPEN e2122320 (2021); *see also infra* Section II (discussing studies assessing the removal of the in-person dispensing requirement, many of which contained all of the 2016 changes in combination).

F. Modification of the Adverse Event Reporting Requirement Was Supported by More Than Adequate Rationale.

Based on the extensive and rigorous scientific evidence, FDA reasonably concluded that the 2016 changes would not alter the safety profile of the original regimen approved in 2000. J.A. 310. Indeed, the rates of serious adverse events in the studies evaluating the proposed 2016 changes were "generally far below 1.0%." J.A. 474. And, FDA had already received 15 years of reporting on serious adverse events associated with mifepristone, which conclusively demonstrated that major adverse events such as excessive blood loss, hospitalization, or surgery are exceedingly rare.[53] As a result, FDA reasonably concluded that reporting on events other than deaths could be collected in periodic safety updates. FDA's modification of the adverse event reporting requirement was reasonable at the time the decision was made, J.A. 506, and confirmed by review of adverse reports submitted in the FAERS database since 2016. J.A. 398.

[53] *See, e.g.,* Upadhyay et al., *Incidence of emergency department visits and complications after abortion*, 125 OBSTET. GYNECOL. 175 (2015) (finding only a 0.31% serious adverse event rate among the 11,319 patients who had medication abortions).

II. FDA's 2021 Decision Removing the In-Person Dispensing Requirement from the REMS, Formalized in 2023, Was Supported by Ample Scientific Evidence.

A. FDA Relied upon Ample Scientific Evidence Supporting the Safety and Effectiveness of Removing the In-Person Dispensing Requirement.

The Fifth Circuit held that FDA's 2021 nonenforcement decision was likely arbitrary and capricious because the literature FDA relied upon "did not affirmatively support its position."[54] App. 61a. However, this conclusion conflicts with the record FDA considered and relied upon while evaluating the in-person dispensing requirement. FDA's decision not to enforce and ultimately to remove the in-person dispensing requirement from the REMS was supported by a thorough scientific review. In addition to reviewing the in-person dispensing requirement in support of

[54] In addition, the Fifth Circuit found that FDA's decision was likely arbitrary and capricious because the Agency relied upon adverse event report data that no longer had data from prescribers because reporting requirements had been modified by the 2016 Amendments. App. 59a. However, FDA had ample evidence to support this change given over 15 years of adverse event reporting indicating that risks occurred rarely. J.A. 319. Further, even after the 2016 change, more extensive reporting of adverse events is required for mifepristone than the vast majority of other medications. *See* Brief of Amici Food and Drug Law Scholars as Amicus Curiae in Support of Petitions for Writ of Certiorari*, FDA v. Alliance for Hippocratic Medicine* at 15 (Oct. 12, 2023). The Fifth Circuit's reasoning, which disregards data from such rigorous reporting requirements would have disruptive effects throughout the regulatory landscape, and prevent FDA from relying on adverse events data derived from anything less than the most stringent reporting requirements.

the April 2021 nonenforcement decision, FDA further analyzed the requirement in December 2021—as described both in a REMS modification rationale review directing manufacturers to apply for a modified REMS, and in a denial of a citizen petition seeking to roll back multiple REMS changes—before formally removing the in-person dispensing requirement in January 2023. FDA considered and cited scientific studies each time that supported the Agency's determination that the in-person dispensing requirement was not necessary to ensure the safety and effectiveness of mifepristone for medication abortion. Indeed, the FDA-reviewed studies far exceeded the statutory requirements.

1. The April 2021 Nonenforcement Decision Was Supported by Ample Scientific Evidence.

As the basis for its April 2021 nonenforcement decision, FDA relied on studies that included clinical outcome data for over 50,000 instances of medication abortion provision. J.A. 364. These studies reviewed safety and effectiveness of care delivered in person, via telemedicine, and through hybrid options in which some but not all stages of care were provided in person (i.e., screening took place via telemedicine but pills were picked up in person, or patients visited a clinic of their choice to receive an ultrasound prior to pills being sent by mail). *Id.* The studies also compared outcomes before and after the COVID-19 public health emergency, which permitted the use of telemedicine for mifepristone and provided a natural experiment for assessing the safety of telemedicine abortion provision. *Id.* FDA concluded that the "overall findings from these studies do not appear to show increases in safety concerns" in the absence of an in-person

dispensing requirement. J.A. 365. Each study FDA relied upon found high effectiveness and high safety rates for medication abortion provision via telemedicine, with patient outcomes consistent with in-person dispensing of mifepristone. *Id.* FDA thus had ample evidence to find that the in-person dispensing requirement was not necessary to ensure the safety and effectiveness of mifepristone.

One such study was an assessment of the TelAbortion Project, a pilot program which was the first in the United States through which patients could obtain an abortion legally without an in-person visit.[55] The study found 95% effectiveness across 1157 patients receiving medication abortion, of which almost all did not have in-person dispensing.[56] This effectiveness rate is comparable to effectiveness for in-person care demonstrated by prior research.[57] Only 0.9% of patients experienced serious adverse events, which is also consistent with serious adverse event rates when mifepristone is delivered in-person.[58] The authors concluded that their "data disprove[d] the notion that medication abortion must be dispensed in-person[.]"[59]

In addition, FDA relied upon a study that directly compared rates of success and safety for 334 patients receiving medication abortion via three methods: telemedicine consultation with pills sent by mail, telemedicine consultation with in-person medication

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[55] Chong et al., *Expansion of direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic*, 104 CONTRACEPTION 43 (2021).

[56] *Id.*

[57] *Id.* (citing Chen, *supra* note 15).

[58] *Id.*

[59] *Id.* at 48.

pick-up, and in-person care provision.[60] The study found similar rates of completion for each method, with entirely remote care having the *highest* effectiveness (97.1% for mailed pills, 95.8% for in-person pill pick-up, and 93.6% for in-clinic care).[61] The study found that all three provision methods had similarly low rates of serious adverse events, and the study authors concluded that the data "does not support that the REMS [requiring an in-person visit] increases the safety of medication abortion."[62]

Further, FDA considered two international studies, one of which included data from a total of 52,142 patients, including 85% of medication abortions taking place in England and Wales during the two months before and two months after COVID-19-related guidelines lifted in-person ultrasound requirements and shifted medication abortion care to telemedicine.[63] This study compared outcomes from 22,158 traditional clinic-based abortions with 29,984 telemedicine abortions. The authors found successful abortions for 98.8% of telemedicine patients compared to 98.2% success rates for in-clinic care, and extremely low rates of serious adverse events for both groups (.02% telemedicine compared to .04% in-clinic).[64] The study also found that telemedicine increased access to care with

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[60] Kerestes et al., *Provision of medication abortion in Hawaii during COVID-19: practical experience with multiple care delivery models*, 104 CONTRACEPTION 49 (2021).

[61] *Id.*

[62] *Id.* at 53.

[63] Aiken et al., *Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study*, 128 BJOG 1464 (2021).

[64] *Id.*

significant reductions in waiting times and gestation at the time of abortion.[65]

A Scotland-based study of 663 patients found 98% completion rates for patients receiving medication abortion following a telephone consultation.[66] All patients took mifepristone at home, and 78.7% of patients determined gestation using last menstrual period, i.e. they did not have an in-person visit prior to obtaining the medication.[67] Low rates of serious adverse events were reported, with only 2 patients (0.3%) being admitted to the hospital.[68]

Based on this extensive data, FDA appropriately determined that waiving and ultimately removing the in-person dispensing requirement would not affect the safety and effectiveness of mifepristone used for medication abortion.

2. Additional Studies Before FDA in 2021 and Relied on in its December 2021 Analyses Supported the Removal of the In-Person Dispensing Requirement.

Additional studies FDA considered in 2021 supported the removal of the in-person dispensing requirement. In analyses issued by FDA in December 2021, the Agency relied on a set of studies which included over 3,000 patients. Two of these studies (Chong et al. and

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[65] *Id.*

[66] Reynolds-Wright et al., *Telemedicine medical abortion at home under 12 weeks' gestation: a prospective observational cohort study during the COVID-19 pandemic*, 47 BMJ SEX REPROD. HEALTH 246 (2021).

[67] *Id.*

[68] *Id.*

Kerestes et al.) had also been considered by FDA in April 2021 and are described above. Two other studies discussed by FDA were additional assessments of the TelAbortion Project, which, like Chong et al., found very low rates of serious adverse events and high rates of completion without follow-up care.[69] One found a 94% completion rate with only two serious adverse events among 217 patients (1%).[70] The other found a 95.6% completion rate and only three serious adverse events among 412 patients (0.7%).[71] The Anger et al. study also compared groups of patients who had a pretreatment ultrasound or pelvic exam to patients who did not and found no statistically significant differences in serious adverse events.[72]

Additional studies analyzed by FDA provided further evidence of the safety and effectiveness of the provision of mifepristone without in-person dispensing. One such study included outcome data for 227 patients who were evaluated for eligibility during a clinic visit and received the medication through a mail-order pharmacy rather than at the clinic visit.[73] The study found a

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[69] Raymond et al., *TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States*, 100 CONTRACEPTION 173 (2019); Anger et al., *Clinical and service delivery implications of omitting ultrasound before medication abortion provided via direct-to-patient telemedicine and mail in the US*, 104 CONTRACEPTION 659 (2021). Many of the participants in these two studies were also in the Chong study. *See supra* note 55.

[70] Raymond et al., *supra* note 69.

[71] Anger et al., *supra* note 69.

[72] *Id.*

[73] Grossman et al., *Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment*, 107 CONTRACEPTION 36 (2022).

96.9% completion rate with only two (0.9%) serious adverse events, which is comparable to wholly in-clinic care.[74] Another study involved 141 patients receiving medication abortion delivered by a mail-order pharmacy after being evaluated through an online form that collected information on pregnancy and medical history.[75] The study found 95% of participants experienced complete abortion without the need for follow-up care, and no serious adverse events were reported.[76] An additional study evaluated the provision of mifepristone through retail pharmacies, including outcomes of 243 patients who received mifepristone in a retail pharmacy following in-clinic evaluation.[77] The study found a 93.5% effectiveness rate, with no serious adverse events.[78]

Based on the record of scientific evidence considered, FDA reasonably concluded that removing the in-person dispensing requirement would not reduce the safety or effectiveness of mifepristone for medication abortion. FDA's decision to remove the requirement was well-supported by the medical evidence, both at the time the decision was made in April 2021 and at later moments of consideration in December 2021.

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[74] *Id.*

[75] Upadhyay (2021), *supra* note 52.

[76] *Id.*

[77] Grossman et al., *Medication abortion with pharmacist dispensing of mifepristone,* 137 OBSTET. GYNECOL. 613 (2021).

[78] *Id.*

B. Additional Evidence Supports the Safety and Effectiveness of Removing the In-Person Dispensing Requirement.

While FDA announced its intention to remove the in-person dispensing requirement in 2021, this decision was formalized in 2023. In the interim, additional studies were published that supported the removal of the in-person dispensing requirement. These studies documented how patients' real-life experiences with medication abortion via telemedicine have continued to be safe and effective, with high effectiveness and low rates of serious adverse events that are very similar to in-clinic dispensing.

One such study examined a cohort of nearly 4,000 patients living across 24 states receiving medication abortion in different settings and found similar rates of effectiveness when medications were dispensed by mail (93.3%) compared to in-person (95.4%); serious adverse events occurred rarely whether medications were dispensed in-person or mailed.[79] A study currently in press assessing the experiences of 6,034 patients across 20 states evaluated the effectiveness and safety of asynchronous telemedicine for medication abortion, finding 97.7% effectiveness with only 0.3% of patients experiencing serious adverse events, with no significant differences between synchronous or asynchronous models of care.[80] Yet another study evaluating 330 patients found a 93% success rate with only one

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[79] Upadhyay et al., *Outcomes and safety of history-based screening for medication abortion: a retrospective multicenter cohort study*, 182 JAMA INTERNAL MED. 482 (2022).

[80] Upadhyay et al., *Effectiveness and safety of telehealth medication abortion in the United States*, NATURE MED. (2024).

serious adverse event (0.3%).[81] Further, a study reviewing the safety and effectiveness of medication abortion before and after Canada eliminated its REMS-like restrictions on mifepristone and made it available with a normal prescription included outcome data for nearly 280,000 abortions, and found there were no material changes in the incidence of serious adverse events.[82]

In addition, recent studies demonstrate that removal of the in-person dispensing requirement is consistent with the statutory requirements for REMS, which must "not be unduly burdensome on patient access to the drug, considering in particular . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved areas) . . . and . . . patients with functional limitations." 21 U.S.C. §§ 355-1(f)(2)(C). For example, a geospatial analysis of over 6,000 patients living in 31 states and Washington D.C. found that patients who obtained abortion care via telemedicine averted significant travel time by not needing to visit a clinic; virtual care was particularly beneficial for patients who used public transit, who saved a median of 1 hour and 25 minutes of travel time.[83] Given this evidence, the in-person

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[81] Pena et al., *Telemedicine for medical abortion service provision in Mexico: a safety, feasibility, and acceptability study*, 114 CONTRACEPTION 67 (2022).

[82] Schummers et al., *Abortion safety and use with normally prescribed mifepristone in Canada*, 386 N. ENG. J. MED. 57 (2022).

[83] Koenig et al., *The role of telehealth in promoting equitable abortion access in the United States: a spatial analysis*, 9 JMIR PUB. HEALTH & SURVEILLANCE e45671 (2023). Additionally, a retrospective study of medication abortion patients found that dispensing mifepristone by mail did not significantly prolong time from patients' first contact with the clinic to the time of mifepristone ingestion or increase pregnancy duration at

dispensing requirement was inconsistent with the statutory requirements for imposing the REMS elements and was appropriately removed.

These recent studies demonstrating continued safety of telemedicine abortion care further show that FDA's decision to remove the in-person dispensing requirement was reasonable and supported by extensive evidence, consistent with statutory requirements.

CONCLUSION

The Court should grant the relief requested by Petitioners.

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ingestion. Koenig et al., *Mailing abortion pills does not delay care: A cohort study comparing mailed in-person dispensing of abortion medications in the United States*, 121 CONTRACEPTION 109962 (2023).

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APPENDIX

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