Exhibit B

Sept. 29, 2021

BY ELECTRONIC MAIL

Janet Woodcock, M.D.
Acting Commissioner
United States Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Re: Evidence Supporting Elimination of the Mifepristone REMS

Dear Dr. Woodcock:

We are the health care providers and researchers engaged in litigation challenging the Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone 200 mg for termination of early pregnancy. We are pleased that the U.S. Food and Drug Administration ("FDA") has initiated a comprehensive evaluation of the mifepristone REMS and its three elements to assure safe use ("ETASU"), and appreciate the opportunity to submit data and evidence for FDA's review.[1]

As you know, it is our position that a REMS is not medically necessary to ensure that the benefits of mifepristone outweigh its risks.[2] We note that one of the signatories to this letter (the Society of Family Planning) is the organization that represents Complex Family Planning Fellowship-trained obstetrician-gynecologists, who are the leaders in clinical care, medical education, and research relating to abortion and contraception. Other leading medical authorities—including the American Medical Association, the American College of Obstetricians and Gynecologists, and the American Academy of Family Physicians—likewise support eliminating these restrictions.[3] We hope that, following a comprehensive evaluation incorporating new data and evidence from the past five years, FDA will reach the same conclusion.

The Mifepristone REMS with ETASU Does Not Enhance Safety

As extensively detailed in the letter submitted by the Society of Family Planning on August 11, 2021, peer-reviewed scientific evidence, including research published since the most recent FDA-approved labeling change in 2016, confirms that mifepristone is extremely safe and highly effective whether dispensed at a health center, pharmacy, or by home delivery, and does not require a clinician to oversee dispensing or specially certify their ability to provide appropriate care. The evidence is clear that the mifepristone REMS and its three ETASU confer no benefit in terms of safety, efficacy, or acceptability of the medication, are not "commensurate with" the risks of mifepristone,[4] and create barriers to use that reduce patient access and negatively impact public health, causing particular harm to communities of color, people with fewer resources, and people living in rural areas.

Mifepristone's strong safety and efficacy findings hold true across a range of regulatory contexts, including international and domestic studies operating outside of the ETASU C dispensing framework. For instance, as you are aware,[5] a recent large (N=52,218) retrospective cohort study reported on the safety, efficacy, and acceptability of telemedicine abortion at Britain's

largest abortion providers, which rapidly adapted to provide medication abortion using telemedicine during the spring and summer of 2020 in response to the COVID-19 pandemic.[6] Following a telehealth consultation, individuals with a last menstrual period dating the pregnancy up to 69 days and without symptoms of ectopic pregnancy were able to receive both mifepristone and misoprostol by mail for home administration. Aiken and colleagues found that medication abortion was equally effective in this telemedicine model (98.8%) versus the traditional in-clinic mifepristone administration model (98.2%, p=1.0); that 99.98% of patients using the telemedicine model experienced no serious adverse events compared to 99.96% of abortions with an in-person assessment; and that patients obtaining their medications by mail following a telemedicine consultation were able to initiate treatment *earlier* in pregnancy than patients utilizing the traditional in-clinic model. Similarly, in a large (N=1,157 abortions) national U.S.-based clinical trial of mifepristone dispensing by mail (the TelAbortion study), Chong and colleagues found that mifepristone dispensing by direct mail to consumers is effective (95% abortion completion with medication alone), with only 0.9% experiencing any serious adverse event, compared to a serious adverse event rate of 0.65% in a large (N=233,805 medication abortions) retrospective cohort study of in-clinic mifepristone administration.[7]

There is likewise no evidence that the ETASU A requirement that mifepristone prescribers attest to their ability to prescribe mifepristone mitigates any safety risks of the medication. Indeed, the evidence refutes this. For instance, in Canada, mifepristone-specific requirements for provider certification were lifted in November 2017. According to a comprehensive analysis of linked medical and financial records in Ontario, medication abortion remained extremely safe after deregulation, with a major complication rate of 0.33% compared to a rate of 0.31% in an analysis of a similar administrative dataset from California under the REMS, and consistent with a clinical review finding major complication rates below 1% across multiple studies of mifepristone use for early abortion.[8]

Finally, we agree with the recommendation of FDA's scientific review team in 2016 to eliminate ETASU D, after finding that this ETASU "does not add to safe use conditions" because the Patient Agreement is "generally duplicative of information contained in the Medication Guide and of information and counseling provided to patients under standard informed consent practices for medical care and under professional practice guidelines."[9]

The Mifepristone REMS Is an Outlier and Unwarranted by Mifepristone's Strong Safety Record

Consistent with strict statutory criteria,[10] FDA imposes REMS programs rarely: fewer than 3% of FDA-regulated drugs are subject to a REMS,[11] and the overwhelming majority of drugs subject to a REMS are opioids—which, in FDA's words, are "claiming lives at [such] a staggering rate" that they are "reducing life expectancy in the United States."[12] FDA subjects only 17 drugs (0.09%), including Mifeprex® and its generic, to a REMS requiring the patient to obtain the medication in a clinic, office, or hospital.[13] And for all such drugs *except* mifepristone, FDA also requires that the medication be taken under clinical supervision, either because of the administration form (e.g., intravenous) or because it can be safely administered only in certain settings (e.g., with monitoring for immediate reactions such as "life-threatening respiratory depression"). In short, mifepristone is the only drug in the nation that FDA requires patients to

pick up in a clinical setting yet permits patients to self-administer elsewhere without direct clinical supervision, based on data confirming the safety of home administration.[14]

While we recognize that there are multiple factors informing the determination of whether a REMS is necessary for any individual drug,[15] we note that FDA has determined that many other drugs posing risks of serious adverse events can be successfully regulated through labeling without a REMS. For example:

- Jeuveau® is an FDA-approved acetylcholine release inhibitor and a neuromuscular blocking agent "indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients"—i.e., it is indicated for a purely cosmetic purpose among a healthy population. Jeuveau carries a black-box warning for "[s]wallowing and breathing difficulties" that "can be life threatening" if this botulinum toxin product spreads beyond the area of injection, and the labeling notes that "there have been reports of death."[16]
- Propecia®, a drug "indicated for the treatment of male pattern hair loss," had its labeling updated in 2011 to reflect that this cosmetic medication may cause an "increased risk of high-grade prostate cancer."[17]
- NuvaRing® is an estrogen/progestin combination hormonal contraceptive ("CHC") inserted as a vaginal ring, which carries a black-box warning for "serious cardiovascular events" with increased risk among cigarette smokers.[18] Its labeling warns patients that CHCs pose a risk of "death from heart attack, blood clots or stroke."[19] Other serious risks associated with NuvaRing include Toxic Shock Syndrome and liver tumors.[20]
- Coumadin®, a common anticoagulant, carries a black box warning for "major or fatal bleeding," with risk ranging from 0.6 to 4.6% for patients with certain comorbidities.[21]

For all of these drugs, FDA has determined that the benefits outweigh the risks even in the absence of a REMS. Now, with the benefit of additional safety and efficacy data on mifepristone reported over the past five years, we urge you to find that mifepristone's risks likewise can be appropriately managed through labeling without a REMS.

The Mifepristone ETASU Are Unduly Burdensome

The REMS statute prohibits ETASU that are "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)."[22] The statute further requires that any ETASU be crafted to "minimize the burden on the health care delivery system," "[t]o the extent practicable."[23]Accordingly, FDA has emphasized that a "REMS should be designed to meet the relevant goals, not unduly impede patient access to the drug, and minimize the burden on the health care delivery system to the extent practicable."[24] While a drug sponsor may request changes to a REMS program, it is FDA that is responsible for ensuring that any REMS comports with all statutory and regulatory requirements and limitations, regardless of what the sponsor has proposed or requested.[25]

The mifepristone ETASU do not comply with these requirements. Extensive evidence shows that these ETASU significantly impede patient access, and do so in part by burdening health care providers. And, whereas FDA has long acknowledged that mifepristone is "important to the health of women,"[26] has underscored the need to prevent treatment delays for mifepristone patients,[27] and has stressed that unwanted pregnancy can be a "serious medical condition,"[28] substantial evidence shows that the mifepristone ETASU *cause* treatment delays and prevent some pregnant patients from obtaining a desired abortion at all.

Attached as appendices are several declarations that were submitted as part of the *Chelius v. Becerra* litigation, which provide first-hand physician narratives, research, and statistical analysis detailing how the mifepristone ETASU unduly burden the health care delivery system and patients' access to this medication. We appreciate your consideration of all of this relevant evidence, which we briefly summarize below:

First, the mifepristone ETASU reduce the pool of qualified clinicians providing medication abortion, including in the geographic areas most lacking in abortion access. For instance, in a nationally representative survey of currently practicing board-certified obstetrician-gynecologists, fewer than one in five respondents who see patients seeking abortion care reported having provided a medication abortion during the previous year—but the proportion of medication abortion providers would likely *double* if clinicians were permitted to prescribe mifepristone through a pharmacy.[29] Notably, the number of respondents in the South and Midwest who said they would begin providing medication abortion if not for the REMS was higher than the number who were currently providing such care.[30] This finding is of particular significance given the increasing efforts by states in the South and Midwest to ban abortion at all but the earliest weeks of pregnancy.[31] Put plainly, if there are more medication abortion providers in those states, more patients will be able to obtain abortions before confronting those (unconstitutional) gestational age limits. Moreover, while the overwhelming majority of current abortion providers practice in urban areas, 40% of OB-GYNs who responded that they would provide medication abortion care if not for the REMS identified their practices as "suburban" or "midsize town, rural, or military."[32]

Specifically, ETASU C burdens the health care delivery system and severely reduces patient access because of the challenges of obtaining institutional approval to dispense mifepristone onsite, and the complicated logistics necessary to do so. It is extremely unusual for health care providers to have to serve as, in effect, both prescribers and pharmacists; as noted above, fewer than 0.1% of FDA-approved drugs must be dispensed in a hospital, medical office, or clinic. Thus, health care institutions typically must develop unique protocols around the dispensing of mifepristone onsite, which can significantly delay clinicians' ability to prescribe this medication or prevent them from doing so at all. As just one example, it took five years and hundreds of hours of individual clinician and stakeholder advocacy before mifepristone was available to patients at the University of Michigan's Women's Clinic. After years of clinician lobbying to add mifepristone to the institution's formulary, personnel across the organization then had to develop protocols for ordering, storing, and dispensing the medication (including "opt-out" protocols for staff opposed to any involvement in such activities), as well as establish insurance and billing practices. Many clinicians would face none of these burdens if their patients could simply fill their mifepristone prescription through a retail or mail-order pharmacy.

Additionally, ETASU C exacerbates these logistical burdens by enabling interference by individuals opposed to abortion. Instead of being able to simply issue a mifepristone prescription for an eligible patient to fill at a pharmacy, clinicians seeking to prescribe mifepristone must—as a direct result of ETASU C—involve numerous other health care staff in the process of procuring, stocking, dispensing, and billing for mifepristone onsite. As a practical matter, this means that even a single colleague who objects to abortion can substantially delay, or altogether derail, a clinician's ability to prescribe a safe and effective medication that their patients urgently need.

ETASU A also deters many qualified clinicians from becoming mifepristone prescribers. In light of the long history of anti-abortion violence and harassment in this country, some physicians are unwilling to register with the mifepristone sponsors—fearful of what they and their families might face if abortion opponents were ever able to access their certification agreements. While the drug manufacturers and distributors are required to maintain that information strictly confidentially, these clinician fears are not unfounded; indeed, in our litigation, FDA was unwilling to provide Plaintiffs with the names or offices of agency staff who had been involved in any Mifeprex reviews, *even subject to a protective order* requiring strict confidentiality of Plaintiffs and their counsel.[33] Prescriber certification presents a real barrier to patient access, and, as discussed above, there is no evidence showing that this ETASU advances any countervailing safety interest sufficient to outweigh these burdens.

Second, ETASU C forces patients to travel unnecessarily to a mifepristone provider for no medical reason, and in sharp contrast with the expansion of telemedicine nationwide. Across virtually all other areas of medicine, a telemedicine revolution is increasing health care access in medically under-resourced communities and reducing the need for patients to travel long distances for care. But, while medically eligible mifepristone patients already can and do obtain all evaluation and counseling via telemedicine, the REMS prohibits patients from filling their prescription by mail or at a local pharmacy. Instead, FDA requires that mifepristone patients travel to a health center for the sole purpose of picking up the pill and signing a form.

It is important to understand that abortion access is very limited in the United States—in part due to the burdens of ETASU C and A, which reduce the number of clinicians able to provide this essential health care. A nationally representative sample of 8,000 abortion patients found that patients traveled, on average, 68 miles round-trip to receive an abortion.[34] In a majority of states, at least 20% of reproductive-age women live more than 100 miles round-trip from the nearest abortion clinic.[35] And while rural areas are particularly lacking, patients in urban areas also struggle. A 2018 study found that 27 major cities have no publicly advertised abortion provider within 100 miles.[36] Requiring patients to pick up their mifepristone pill in person at a health center thus in many cases requires significant travel.

Given the mifepristone patient population, such travel can be incredibly difficult and in some cases impossible. According to a nationally representative survey, in 2014 (the most recent year for which such data are available), 75 percent of abortion patients had incomes at or below the U.S. Official Poverty Measure.[37] Sixty percent of abortion patients identify as people of color, including 53 percent of patients who identify as Black or Hispanic.[38] And 60 percent of abortion patients have at least one child.[39] Forcing patients to travel in person to pick up the mifepristone tablet at one of the (few) abortion providers in the country imposes costs and burdens relating to

transportation, childcare, and lost wages for missed work that many in this patient population simply cannot afford. Indeed, a robust body of research, spanning multiple states and decades, confirms that forcing patients to travel even slightly farther (e.g., 10 miles) delays or blocks patients from accessing desired abortions.[40] In short, these ETASU specifically burden "patients who have difficulty accessing health care," in violation of the REMS statute.[41]

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We welcomed FDA's April 2021 announcement that it intends to exercise enforcement discretion during the COVID-19 Public Health Emergency with respect to the dispensing of mifepristone through the mail or through a mail-order pharmacy when such dispensing is done by or under the supervision of a certified prescriber. We note that this enforcement discretion has mitigated some (though not all) of the burdens on patients and the health care delivery system described in the physician narratives attached as Appendices. Most significantly, enabling patients to obtain their mifepristone prescription through telemedicine and mail-order pharmacies where medically appropriate has prevented many patients from having to needlessly travel for health care during the pandemic, reducing treatment delays and COVID-19 risks and enabling some patients to access mifepristone who otherwise would not have been able to do so at all.

In addition, having the option to submit a prescription to a pharmacy and then have the pharmacy directly bill and dispense the mifepristone to their patient has enabled some qualified physicians—who previously had been impeded by the complex logistics and controversy around procuring, stocking, dispensing, and billing for mifepristone onsite at their health centers—to begin prescribing this medication for the first time. This is consistent with the nationally representative OB-GYN survey discussed above, which showed that eliminating the REMS would increase the pool of qualified mifepristone prescribers.[42] If the other barriers imposed by the mifepristone ETASU are lifted, even more qualified clinicians will be able to begin prescribing this safe and effective medication.

We appreciate FDA's careful consideration of the extensive evidence showing that the mifepristone REMS does not advance patient safety; causes treatment delays that undermine patients' health; subjects some patients who are unable to obtain mifepristone because of the REMS to the serious medical risks of ongoing pregnancy and childbirth; and unduly burdens both patients and the health care delivery system, with disproportionate harm to people living in rural and medically underserved areas, people with fewer financial resources, and people of color. Consistent with this sound evidence, we urge you to eliminate the mifepristone REMS.

Sincerely,

Dr. Graham Chelius
The Society of Family Planning
The California Academy of Family Physicians

Plaintiffs in *Chelius v. Becerra*, No. 1:17-cv-00493-JAO-RT (D. Haw.)

CC: Dr. Patrizia Cavazzoni, Center for Drug Evaluation and Research
Dr. Catherine Sewell, Center for Drug Evaluation and Research

[1] *Chelius v. Becerra*, No. 1:17-cv-00493-JAO-RT (D. Haw.) [hereinafter *Chelius v. Becerra*], Joint Motion to Stay Case Pending Agency Review 2, Dkt. 148.

[2] 21 U.S.C. § 355-1(g)(4)(B)(i).

[3] *See, e.g.*, House of Delegates, Am. Med. Ass'n, *Memorial Resolutions Adopted Unanimously* No. 504 (2018), https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/hod/a18-resolutions.pdf; Am. Coll. of Obstetricians & Gynecologists, *Position Statement: Improving Access to Mifepristone for Reproductive Health Indications* (June 2018), https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications; Cong. of Delegates, Am. Acad. of Fam. Physicians, *Resolution No. 506 (CoSponsored C) Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization on Mifepristone* (May 24, 2018), https://www.reproductiveaccess.org/wp-content/uploads/2019/02/Resolution-No.-506-REMS.pdf.

[4] 21 U.S.C. § 355-1(f)(2)(A).

[5] *See* Letter from Janet Woodcock, M.D., Acting Commissioner of Food & Drug Admin., to Maureen G. Phipps, M.D., M.P.H., FACOG, and William Grobman, M.D., M.B.A. (Apr. 12, 2021), https://www.aclu.org/letter/fda-response-acog-april-2021.

[6] Abigail Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided Via Telemedicine: A National Cohort Study*, 128(9) BJOG 1464 (Aug. 2021), https://obgyn.onlinelibrary.wiley.com/doi/10.1111/1471-0528.16668.

[7] Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience during the COVID-19 Pandemic*, 104(1) Contraception 43 (July 2021), https://www.contraceptionjournal.org/article/S0010-7824(21)00091-3/fulltext; Kelly Cleland et al., *Significant Adverse Events and Outcomes after Medical Abortion*, 121(1) Obstetrics & Gynecology 166 (Jan. 2013), https://pubmed.ncbi.nlm.nih.gov/23262942/.

[8] Laura Schummers et al, *Do Medication Abortion Complications Increase When Restrictive Risk Evaluation and Mitigation Strategy Regulations are Removed? A Population-Based Study Using Single-Payer Linked Health Administrative Data*, 102(4) Contraception 273 (Oct. 2020), https://www.contraceptionjournal.org/article/S0010-7824(20)30214-6/fulltext; Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications after Abortion*, 125(1) Obstetrics & Gynecology 175 (Jan. 2015), https://pubmed.ncbi.nlm.nih.gov/25560122/; Nathalie Kapp & Patricia A. Lohr, *Modern Methods to Induce Abortion: Safety, Efficacy and Choice*, 63 Best Prac. & Res. Clinical Obstetrics & Gynecology 37 (Feb. 2020), https://www.sciencedirect.com/science/article/pii/S1521693419301762?via%3Dihub.

[9] U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., *Application Number 020687Orig1s020: Summary Review(s)* 25 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020SumR.pdf; U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., *Application Number 020687Orig1s020: Risk Assessment and Risk Mitigation Review(s)* Ref ID: 3909589 at 2 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RiskR.pdf.

[10] 21 U.S.C. § 355-1(a)(1).

[11] *Chelius v. Becerra*, Joint Stips. of Facts, Dkt. 140, ¶¶ 59–60.

[12] *Id.* at ¶¶ 59–60; U.S. Food & Drug Admin., *Opioid Medications* (Mar. 29, 2021), https://www.fda.gov/drugs/information-drug-class/opioid-medications.

[13] *Chelius v. Becerra*, Joint Stips. of Facts, Dkt. 140, ¶¶ 59, 61.

[14] U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., *Application Number 020687Orig1s020: Medical Review(s)* 39 (Mar. 29, 2016) https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.

[15] 21 U.S.C. § 355-1(a)(1).

[16] U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., *Application Number 761085Orig1s000: Labeling* (Jeuveau) (Feb. 2019), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/761085Orig1s000Lbl.pdf.

[17] U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., *Labeling* (Propecia) (Apr. 2012), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020788s020s021s023lbl.pdf.

[18] U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., *Labeling* (NuvaRing) (Oct. 2013), https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021187s022lbl.pdf.

[19] *Id.*

[20] *Id.*

[21] U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., *Labeling* (Coumadin) (Oct. 2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/009218s107lbl.pdf.

[22] 21 U.S.C. § 355-1(f)(2)(C).

[23] 21 U.S.C. § 355-1(f)(2)(D).

[24] U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., Ctr. for Bio. Eval. & Res., *REMS: FDA's Application of Statutory Factors in Determining When a REMS Is Necessary* 5 (April 2019), https://www.fda.gov/media/100307/download.

[25] 21 U.S.C. § 355-1(a), (d), (f).

[26] U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., *Mifeprex (mifepristone) NDA Approval Letter* 4 (Sept. 2000), *Chelius v. Becerra*, Dkt. 142-2, Ex. B.

[27] U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., *Final Risk Evaluation and Mitigation Strategy (REMS) Review: Mifeprex* (Oct. 2013), *Chelius v. Becerra*, Dkt. 85-8.

[28] Letter from Janet Woodcock, M.D., Director, Ctr. for Drug Eval. & Res., to Donna Harrison, M.D. et al., Denying Citizen Petition Asking the FDA to Revoke Approval of Mifeprex 4-5 (Mar. 29, 2016) (emphasis added), https://www.regulations.gov/document?D=FDA-2002-P-0364-0002.

[29] Sara Daniel et al., *Obstetrician-Gynecologist Willingness to Provide Medication Abortion with Removal of the In-Person Dispensing Requirement for Mifepristone*, 104(1) Contraception 73 (July 2021), https://www.contraceptionjournal.org/article/S0010-7824(21)00098-6/fulltext.

[30] *Id.*

[31] *See, e.g.*, *Whole Woman's Health v. Jackson*, No. 21A24, 2021 WL3910722 (U.S. Sept. 2, 2021) (denying request to block Texas's six-week abortion ban from taking effect); *Planned Parenthood S. Atl. v. Wilson*, No. 3:21-24 00508-MGL, 2021 WL 672406, at *2 (D.S.C. Feb. 29, 2021) (preliminary injunction of South Carolina six-week ban), *appeal filed*, No. 21-1369 (4th Cir. Apr. 5, 2021); *SisterSong Women of Color Reprod. Justice Collective v. Kemp*, 472 F. Supp. 3d 1297, 1312 (N.D. Ga. 2020) (preliminary injunction of Georgia six-week ban), *appeal filed*, No. 20-13024 (11th Cir. Aug. 11, 2020); *Memphis Ctr. for Reprod. Health v. Slatery*, No. 3:20-CV-00501, 2020 WL 4274198, at *2 (M.D. Tenn. July 24, 2020) (preliminary injunction of Tennessee six-week ban), *appeal filed*, No. 20-5969 (6th Cir. Aug. 24, 2020); *Preterm-Cleveland v. Yost*, 394 F. Supp. 3d 796, 804 (S.D. Ohio 2019) (preliminary injunction of Ohio six-week ban); *EMW Women's Surgical Ctr., P.S.C. v. Beshear*, No. 3:19-CV-178-DJH, 2019 WL 1233575, at *2 (W.D. Ky. Mar. 15, 2019) (temporary restraining order of Kentucky six-week ban).

[32] Daniel et al., *supra* n.29.

[33] *Chelius v. Becerra*, Joint Stips. of Facts, Dkt. 140, ¶ 47 ("In light of the violence and harassment surrounding the provision of abortion, FDA withheld FDA employee names and other identifying information from documents related to Mifeprex in the administrative record . . . . Because releasing this information would constitute an unwarranted invasion of personal privacy and could expose those employees to threats, intimidation, harassment and/or violence, FDA believes it is necessary not to disclose information that could be used to identify these employees to any person outside of FDA, including Plaintiffs' counsel subject to a protective order.").

[34] Liza Fuentes & Jenna Jerman, *Distance Traveled to Obtain Clinical Abortion Care in the United States and Reasons for Clinic Choice*, 28 J. Women's Health 1623, 1625 (2019), https://pubmed.ncbi.nlm.nih.gov/31282804/.

[35] Jonathan M. Bearak et al., *Disparities and Change Over Time in Distance Women Would Need to Travel to Have an Abortion in the USA: A Spatial Analysis*, Lancet Pub. Health e493, e495–96 (2017), https://www.thelancet.come/action/showPDF?pii=S2468-2667%2817%2930158-5 (in six states, a majority of women of reproductive age live more than 50 miles away from the nearest abortion provider, including two states where a majority live more than 150 miles from the nearest provider).

[36] Alice Cartwright et al., *Identifying National Availability of Abortion Care and Distance from Major US Cities: Systematic Online Search*, 20 J. Med. Internet Res. 7 (2018), https://www.jmir.org/2018/5/e186/.

[37] Jenna Jerman et al., Guttmacher Inst., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008* 1, 7 (May 2016), https://www.guttmacher.org/report/characteristics-us-abortion-patients-2014.

[38] *Id.* at 1, 5; *Abortion Surveillance — United States, 2018*, Ctrs. for Disease Control & Prevention [hereinafter *CDC Abortion Surveillance*], at Table 5, https://www.cdc.gov/mmwr/volumes/69/ss/ss6907a1.htm#T5_down (last updated Nov. 7, 2020).

[39] Jerman et al., *supra* n.37, at 1, 7; *CDC Abortion Surveillance* at Table 7, https://www.cdc.gov/mmwr/volumes/69/ss/ss6907a1.htm#T7_down.

[40] Jill Barr-Walker et al., *Experience of Women Who Travel for Abortion: A Mixed Methods Systematic Review*, PLOS ONE 14(4), at 2 (2019), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0209991; Daniel Grossman et al., *Change in Distance to Nearest Facility and Abortion in Texas, 2012 to 2014*, 317 JAMA Network 437, 437–38 (2017), http://sites.utexas.edu/txpep/files/2017/10/Grossman-et-al-HB2-Change-in-Distance-Abortion-JAMA-2017.pdf (in Texas, when the distance to the nearest abortion clinic increased by 25–49 miles, abortions decreased 25.3%; when the change was 50–99 miles, abortions decreased by 35.7%; and when the change was 100 miles or more, abortions decreased by 50.3%); Sharon A. Dobie et al., *Abortion Services in Rural Washington State, 1983–1984 to 1993–1994: Availability and Outcomes*, 31 Fam. Plan. Persp. 241, 241–44 (1999), https://www.guttmacher.org/sites/default/files/article_files/3124199.pdf (in Washington, when a decline in the number of abortion providers led to a 12 mile increase in travel distance for rural women, the abortion rate among that population decreased by 27%); Robert W. Brown et al., *Provider Availability, Race, and Abortion Demand*, 67 Southern Eco. J. 656, 658 (2001) (in Texas, an increase of 10% in the travel distance from a woman's county to the nearest city with an abortion provider was associated with a 2.3% decline in the abortion rate for white women, 2.7% for African-American women, and 5.0% for Hispanic women); James D. Shelton et al., *Abortion Utilization: Does Travel Distance Matter?*, 8 Fam. Plan. Persp. 260, 260–62 (1976), https://jstor.org/stable/pdf/2134397.pdf?seq=1#page_scan_tab_contents (in Georgia, for every 10 miles of distance from the major abortion providers in Atlanta, the number of abortions declined by 6.7 per 1,000 live births); Alison H. Norris et al., *Abortion Access in Ohio's Changing Legislative Context, 2010–2018*, 110 Am. J. Pub Health 1228, 1232 (2020), https://pubmed.ncbi.nlm.nih.gov/32437269/ (abortion rate in rural counties disproportionately affected by clinic closures decreased more than 30% over study period); Ushma D. Upadhyay et al., *Denial of Abortion Because of Provider Gestational Age Limits in the United States*, Am. J. Pub. Health 1687, 1689 (2014), https://doi.org/10.2105/AJPH.2013.301378 (finding that 58.3% of patients turned away because they were beyond the abortion clinic's limit and 67% arriving just before the limit attributed their delay to "travel and procedure costs" and 29.8% cited "not knowing how to get to a provider"; for first trimester patients, travel and procedure cost was the second-most cited reason for delay).

[41] 21 U.S.C. 355-1(f)(2)(C)(ii).

[42] Daniels et al., *supra* n.29.