ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al. Defendants.	NO. 1:23-cv-03026-TOR DECLARATION OF ANDREW HUGHES IN SUPPORT OF PLAINTIFF STATES' REPLY RE MOTION FOR PRELIMINARY INJUNCTION

I, Andrew Hughes, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am an Assistant Attorney General with the Washington State Office of the Attorney General.

3. Attached hereto as Exhibit A is a true and correct copy of the October 4, 2022 Citizen Petition of the American College of Obstetricians and Gynecologists (and 48 other organizations).

4. Attached hereto as Exhibit B is a true and correct copy of the September 29, 2021 Letter from *Chelius* Plaintiffs to the FDA.

5. Attached hereto as Exhibit C is the Appendix to the September 29, 2021 Letter from the *Chelius* Plaintiffs to the FDA.

6. Attached hereto as Exhibit D is a true and correct copy of the March 30, 2020 letter of then-California Attorney General Xavier Becerra and other Attorneys General to HHS and the FDA.

7. Attached hereto as Exhibit E is a true and correct copy of the November 3, 2015 letter to the FDA signed by the American Public Health Association (Population, Reproductive, and Sexual Health Section); Gynuity Health Projects; Ibis Reproductive Health; the National Abortion Federation; and clinicians from the Albert Einstein College of Medicine, Columbia University, Princeton University, Stanford University, the University of California San Francisco, the University of North Carolina, the University of New Mexico and the University of Ottawa, among others.

8. Attached hereto as Exhibit F is a true and correct copy of the November 4, 2015 letter to the FDA from the American College of Obstetricians and Gynecologists.

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

9. Attached hereto as Exhibit G is a true and correct copy of the transcript of the Remarks of Secretary Xavier Becerra at the Press Conference in Response to President Biden's Directive following Overturning *Roe v. Wade* delivered June 28, 2022.

10. Attached hereto as Exhibit H is a true and correct copy of the June 20, 2019 letter of the American Academy of Family Physicians to the FDA.

11. Attached hereto as Exhibit I is a true and correct copy of the Complaint in *American College of Obstetricians & Gynecologists v. FDA*, 8:20-cv-01320-TDC (D. Md.) filed May 27, 2020.

12. Attached hereto as Exhibit J is a true and correct copy of the August 13, 2021 letter from the Society of Family Planning to the FDA.

13. Attached hereto as Exhibit K is a true and correct copy of the October 6, 2021 letter from The American College of Obstetricians and Gynecologists to the FDA.

14. Attached hereto as Exhibit L is a true and correct copy of the June 21, 2022 letter from The American College of Obstetricians and Gynecologists and the American Medical Association to the FDA.

15. Attached hereto as Exhibit M is a Chronology of FDA Communications that I prepared.

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 24th day of March, 2023 at Seattle, Washington.

s/Andrew Hughes
Andrew Hughes
Assistant Attorney General

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

CERTIFICATE OF SERVICE

I hereby certify that on March 24, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF System, which in turn automatically generated a Notice of Electronic Filing (NEF) to all parties in the case who are registered users of the CM/ECF system. The NEF for the foregoing specifically identifies recipients of electronic notice.

DATED this 24th day of March, 2023, at Seattle, Washington.

/s/Kristin Beneski
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Exhibit A

October 4, 2022

TO:

Lauren Roth
Associate Commissioner for Policy
The US Food & Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20903

CITIZEN PETITION

The American College of Obstetricians and Gynecologists submits this petition on behalf of itself and 48 other organizations listed below pursuant to 21 C.F.R. § 10.30 to request that the Food & Drug Administration (FDA) ask Danco Laboratories, LLC ("Danco") – the holder of the approved new drug application for Mifeprex (mifepristone)—to submit a Supplemental New Drug Application (sNDA) that seeks to add miscarriage management as an indication to the drug's label and to eliminate or modify mifepristone's Risk Evaluation and Mitigation Strategy (REMS) so that it is not unduly burdensome for that use.[1] In the meantime, Petitioners also request that FDA immediately exercise enforcement discretion with respect to the use and distribution of mifepristone for miscarriage management without complying with the REMS.[2]

[1] There is precedent for such a request. In 1997, the FDA issued a notice encouraging the manufacturers of certain contraceptives to submit a New Drug Application that would modify the dose and use of its product for postcoital emergency contraception (1). The FDA found that this use was safe and effective, that postcoital emergency contraception was important for public health, and that manufacturers should make this product available. In this case, we are asking the FDA to request the manufacturer to submit an sNDA, as opposed to an NDA, because it is more efficient and the medication abortion drug dosages are identical to the miscarriage management protocol, which was not true in the emergency contraception example.

[2] There also is precedent for FDA to exercise enforcement discretion with respect to REMS requirements when they are seriously affecting patient access to important drugs, as it did last year, for example, with respect to the Clozapine REMS (2). Of course, FDA also exercised enforcement discretion with respect to part of the mifepristone REMS itself in order to facilitate patient access during the COVID-19 public health emergency (3).

Mifepristone, in combination with misoprostol, is the most effective regimen for medical management of miscarriage,[3] but patient access to this regimen is currently limited both because the drug lacks FDA approval for this indication and because the REMS limits clinicians' ability to use the drug for miscarriage management. We urge the FDA to request Danco to seek FDA approval of a miscarriage management indication for mifepristone because it is a safe and essential part of the most effective regimen for miscarriage management. With this new indication on the labeling, the REMS must be eliminated or modified so that it does not unduly burden access to the drug for this use and so that it accurately reflects the approved indications for mifepristone.

ACTION REQUESTED

Petitioners request that the FDA ask Danco to submit an sNDA to add miscarriage management as an indication to the mifepristone label and to modify the REMS so that it does not unduly burden its use for miscarriage management. While the FDA is considering these changes, Petitioners request that FDA state that it will exercise enforcement discretion with respect to the use and distribution of mifepristone consistent with the requested indication and REMS modifications.

STATEMENT OF GROUNDS

[3] HHS Secretary Becerra called mifepristone the "gold standard for care when someone who's pregnant experiences a miscarriage" (4). Indeed, the American College of Obstetricians and Gynecologists recommends using mifepristone in combination with misoprostol whenever available, citing studies we discuss below (5). Nevertheless, the REMS's restrictions have made it difficult for this best practice for miscarriage care to become the standard of care as it ought to be, for reasons we explore in more depth below.

Miscarriage is common, has significant physical, psychological, and social sequelae, and is a contributor to—and result of— racial health inequities. Miscarriage describes the spontaneous loss of a pregnancy prior to 20 weeks' gestation (6). Miscarriage is most common early in pregnancy (7,8). While 1 in 6 recognized pregnancies ends in miscarriage worldwide (7), it is likely that miscarriage also occurs in some early, unrecognized pregnancies. When accounting for unrecognized pregnancies, the miscarriage rate is estimated to be around 25% (8). Miscarriage affects people of every age, race/ethnicity, and socioeconomic status, but is more common among groups negatively impacted by societal dynamics of power and oppression, such as pregnant people[4] who are Black, poor, or exposed to environmental pollutants (7). These risk factors have compounding effects when it comes to health equity, as people of color are both more likely to be exposed to pollution and more likely to live in poverty (9,10).

Miscarriage can also levy a heavy psychological toll, and the burdens of these negative mental health sequelae further exacerbate health inequities. In a recent prospective study in the United States, 1 in 4 people who experienced miscarriage were at risk for major depression 30 days after their loss, according to their scores on a widely used and validated screener (11). Among participants in this study, people who identified as Black had significantly higher odds than people who identified as non-Black of being at risk for major depression following miscarriage, after adjusting for potential confounding medical and demographic differences (aOR 2.48; 95% CI 1.28-4.81) (11). Miscarriage is also stigmatized in many societies and social groups, meaning people who experience pregnancy loss are socially marked as inferior and may be treated poorly or suffer lower self-esteem (12).

[4] Women are not the only people capable of becoming pregnant and not all women are capable of pregnancy. To be inclusive of the diversity of pregnancy-capable individuals, including girls, non-binary people, and trans men, we use gender neutral language in this petition whenever appropriate. However, when referring to studies that only included (presumably cisgender) women or when discussing the gendered impact of regulations, we use gendered language.

The risks and negative outcomes associated with miscarriage are mitigated when health care teams support patient autonomy in selecting a management strategy when appropriate (13). Miscarriage management options are particularly important for patients who experience missed or incomplete miscarriage, where the body has not expelled all of the pregnancy tissue on its own. Without proper care and intervention when needed, miscarriage carries risks of hemorrhage, sepsis, and death (14). Second trimester miscarriage (14 weeks 0 days through 19 weeks 6 days gestation) can carry significant medical risks, and expectant management is not routinely recommended (5). However, for the estimated greater than 80% of miscarriages occurring in the first trimester (8), several management strategies may be appropriate. In general, there are three options for miscarriage management: expectant management, where no interventions are initiated immediately but patients are actively monitored for symptoms indicating that intervention could be needed (e.g., infection); medical management, where medications are used to help the body start or complete the miscarriage process; and surgical management, where a procedure is used to empty the uterus. (5,14) Each option has its own unique risks and benefits, and patients often have strong preferences on which option they prefer. Widely accepted and used clinical guidelines support engaging uncomplicated patients who are experiencing miscarriage in a shared decision-making process, wherein clinicians educate patients on available treatment options so they may make informed choices aligned with their values and preferences (5).

Some patients prefer active intervention because both medical and surgical management on average lead to a faster completion of the pregnancy loss and involve fewer unplanned procedural interventions compared to expectant management. While expectant management can take up to 8 weeks to result in complete miscarriage, many observational studies and randomized

trials affirm that medical management of miscarriage results in markedly faster resolution of the pregnancy, often within a few hours and usually not more than a few days after initiating treatment (15, 16, 17, 18). People who start medication treatment are also less likely to require a subsequent uterine evacuation to complete their miscarriage compared to those who pursue expectant management. For example, in a randomized controlled trial of 1,200 pregnant patients, individuals who were randomized to expectant management were more likely to need unplanned surgical intervention to complete their miscarriage (44%) compared to those randomized to medical treatment of miscarriage (13%) (15). Some patients might also prefer active miscarriage management for psychosocial reasons, including an ability to have some control over an unexpected, and often disheartening, bodily process (7,13). In a randomized controlled trial of people experiencing miscarriages, pregnant individuals who were allocated to expectant management were significantly less likely to state they would choose this method again, compared to those allocated to intervention (18). This trial suggests that the experience of expectant management is on average less acceptable compared to intervention to empty the uterus.

Qualitative research also suggests that choice of management strategy is paramount in driving patient satisfaction with miscarriage care. In a 2017 qualitative study, Wallace and colleagues found that women who had recently experienced miscarriage expressed a strong preference for informed choice among multiple options rather than being prescribed a single option by their health care team (19). The induced abortion patient population, though not perfectly analogous, also provides additional context, with similar findings about the value of method choice across multiple studies. Abortion patients hold strong preferences for method of termination. A 2006 review of the global literature on abortion method preference found that in

most settings and across multiple studies, the predominant reasons patients provide for choosing medication abortion are to avoid surgery and anesthesia, the (incorrect) perception that it is safer than procedural abortion, and the perception that is more natural compared to procedural abortion (20).

Importantly, surgical options are not always available to all patients. Rural patients in particular can struggle to access surgical management of miscarriage due to the lack of trained clinicians in rural communities, meaning that medical management is their only alternative to expectant management (21, 22). The literature is therefore clear that patients value and deserve a choice between expectant management, medical management, and surgical management in the context of miscarriage.

To ensure access to the safest and most effective treatments for miscarriage, and to preserve patient choice in miscarriage management and equitably confer the benefits of that choice irrespective of geographic location, race/ethnicity, and socioeconomic status, it is imperative to promote access to evidence-based medical management of miscarriage, which includes access to mifepristone. To achieve this goal, Danco should request, and FDA should approve, a miscarriage management indication for mifepristone, and the REMS should be revised accordingly. Because the public health needs are urgent, FDA should immediately state that it will exercise enforcement discretion until this process is completed.

I. Miscarriage Management Should be Approved as an Indication for Mifepristone Through the First Trimester of Pregnancy

Miscarriage management should be added to the mifepristone label because it is the most effective regimen for medical management of miscarriage. Published research demonstrates that mifepristone is safe and effective for this use throughout the first trimester (13 weeks and 6 days of pregnancy) (23,24). Indeed, it is as safe or safer than alternatives for miscarriage management and the most effective medical option to manage miscarriage. Patients choosing medical management of miscarriage should have access to the most effective protocol, which is mifepristone in combination with misoprostol.

A. A Combination of Mifepristone and Misoprostol for Miscarriage is the Most Effective Protocol for Medical Management of Miscarriage

Because of the onerous restrictions currently in place on mifepristone in the United States, the most commonly used medical protocol for miscarriage management today is misoprostol alone. However, leading professional organizations encourage the use of adjunctive mifepristone whenever possible.[5] For example, based on a systematic review of the literature on miscarriage management with misoprostol, and on a large, randomized trial of a misoprostol-only regimen, the American College of Obstetricians and Gynecologists (ACOG) recommends an initial dose of 800 micrograms of misoprostol administered vaginally, with a repeat dose administered in the same quantity and route as needed, when utilizing misoprostol alone for miscarriage management (5,17,25,26). However, ACOG further advises that "[t]he addition of a dose of mifepristone (200 mg orally) 24 hours before misoprostol administration may significantly improve treatment efficacy" (5). Clinical experts in internal medicine also endorse

[5] ACOG's practice bulletin notes that "the availability of mifepristone is limited by U.S. Food and Drug Administration Risk Evaluation and Mitigation Strategy restrictions," which makes it inaccessible for miscarriage management in many places (5).

mifepristone use for miscarriage management (27). These recommendations stem from the growing evidence that the mifepristone-misoprostol regimen has superior efficacy for the treatment of miscarriage, compared to misoprostol alone.

In the past decade, two large, randomized trials have augmented the observational literature to definitively prove that misoprostol with adjunctive mifepristone is superior to misoprostol alone to treat miscarriage (23,24,27). Schreiber and colleagues found that 200 milligrams of oral mifepristone followed by 800 micrograms of vaginal misoprostol is more effective (complete expulsion of pregnancy after the initially prescribed regimen = 83.8%; 95% CI 76.8 to 89.3) compared to 800 micrograms of vaginal misoprostol alone (complete expulsion = (67.1%; 95% CI, 59.0 to 74.6) (23). Moreover, the need for uterine aspiration was much lower in the mifepristone-misoprostol group in this trial compared to misoprostol alone (8.8% vs. 23.5%; relative risk, 0.37; 95% CI, 0.21 to 0.68). A separately conducted randomized controlled trial through 14w0d of pregnancy replicated these results, with patients who received mifepristone and misoprostol having a lower risk of not passing their pregnancy within 7 days ([RR] 0.73, 95% CI 0.54-0.99) and a lower risk of needing surgical intervention to empty the uterus ([RR] 0.71, 95% CI 0.53-0.95), compared to misoprostol alone (24).[6] Having enrolled a diverse combined sample of over 1,000 participants across 30 hospitals in the United States and the United Kingdom, together these trials provide excellent evidence of the superiority of the mifepristone-misoprostol regimen compared to misoprostol alone.

B. A Combination of Mifepristone and Misoprostol for Miscarriage is Safe

[6] Chu and colleagues did not directly compare the efficacy of the two originally administered regimens in their trial. Instead, they compared complete miscarriage at 7 days regardless of how many additional doses of misoprostol individuals received on top of the original 800 microgram dose. The difference in completion by 7 days between mifepristone plus a single dose of misoprostol, vs a single dose of misoprostol alone, would likely be larger in magnitude (24).

Medical management of miscarriage has a comparable or superior safety profile than alternatives for miscarriage management. For the context of this discussion, we compare interventions based on the prevalence of (1) transfusion, (2) sepsis, (3) hospitalization, (4) infection without sepsis, and (5) hemorrhage. These serious adverse events are substantially similar to the "serious adverse events" on the mifepristone label for abortion.[7]

When mifepristone and misoprostol was compared to misoprostol alone for first trimester miscarriage, there were no differences in safety outcomes. In two randomized trials that assigned pregnant people to misoprostol alone vs mifepristone with adjunctive misoprostol, there was no difference in the rate of blood transfusions or any other safety outcome (23,24). In a randomized trial including 300 individuals, Schreiber et al reported a serious adverse event (defined as bleeding resulting in transfusion or pelvic infection) rate of 3.4% for mifepristone and misoprostol combined vs 2.0% for misoprostol alone (p=0.47) (23). In a subsequent placebo-controlled trial that enrolled 711 individuals, Chu and colleagues found no difference in bleeding patterns between groups, and a rate of inpatient treatment for infection of 1% among both the misoprostol alone and mifepristone and misoprostol combined groups (24).

C. Abortion Bills are Targeting Mifepristone, Potentially Limiting Access to the Drug for Miscarriage Management and Harming Public Health

Based on the evidence and clinical guidance cited above, clinicians with the political freedom to make evidence-based choices regarding miscarriage treatment are increasingly using mifepristone. For example, in a survey of Massachusetts obstetrician-gynecologists, Neill and

[7] The only serious adverse event on the mifepristone label that we did not include is Emergency Room (ER) visits. ER visits are not a good indicator of safety in the miscarriage population because these patients often first seek care in the ER.

colleagues found that 63% use mifepristone to treat miscarriages (29). However, clinicians in areas where abortion is highly stigmatized and legally scrutinized face many more barriers to this evidence-based best practice. Now that the Supreme Court has overturned *Roe v. Wade*, some states are moving quickly to limit access to drugs that can induce abortion. These efforts have collateral consequences that harm all aspects of reproductive health, including miscarriage management.

The fact that mifepristone is only approved to terminate a pregnancy—even though it is used and is recommended for use off-label for miscarriage management-–has made it vulnerable to wholesale bans on the drug. For instance, in the last legislative session, Alabama legislators introduced Alabama H261, which made it "unlawful for any person or entity to manufacture, distribute, prescribe, dispense, sell, or transfer the 'abortion pill,' otherwise known as RU-486, Mifepristone, Mifegyne, or Mifeprex, or any substantially similar generic or non-generic abortifacient drug in Alabama" (30). A nearly identical bill was also introduced in Arizona (H2811) and other states (31). These are wholesale bans on mifepristone for any use and, if enacted, will prevent clinicians from providing the gold standard miscarriage care in their communities of practice, harming public health. Even without a wholesale ban on mifepristone, clinicians in states that ban abortion may be hesitant to prescribe a drug that has only been approved for abortion even for a legal, off-label use, like miscarriage management (32). Adding miscarriage management to the label would legitimize this important use and potentially hamper legislative efforts to ban the drug so patients have greater access to the most effective medical tool for miscarriage care.

Media reports affirm that out of an abundance of caution, in the wake of *Dobbs v. Jackson Women's Health Organization,* some pharmacies are creating barriers to accessing drugs

that can cause or treat pregnancy loss but are prescribed for other uses, such as methotrexate for rheumatic diseases or mifepristone or misoprostol for miscarriage (33,34,35). Moving forward, regulators and the pharmacy community must work to clarify and educate the field on professional responsibility of pharmacists—by law and by oath—to serve their patients' medical needs and comply with federal law.[8] In this context, including the indication of miscarriage management on the mifepristone label may help to clear up confusion or anxiety about legal compliance in a rapidly evolving legal landscape.

II. The Mifepristone REMS Must Be Eliminated Because it is Not Necessary for the Drug's Benefits to Outweigh its Risks and is Unduly Burdensome for this New Use

If miscarriage management is added as an indication to the mifepristone label, then changes to the mifepristone REMS would also be needed to ensure that it is not unduly burdensome for this new use. Section 505-1(f)(2) of the Federal Food, Drug, and Cosmetic Act states that an Element to Assure Safe Use (ETASU) may "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)." 21 U.S.C. § § 355–1(f)(2). The statute also only permits the imposition of a REMS where it is "necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). And finally, each ETASU must "conform with elements to assure safe use for other drugs with similar, serious risks." 21 U.S.C. § § 355–1(f)(2)

Each element of the mifepristone REMS imposes unique burdens on accessing mifepristone for miscarriage management and is unnecessary to ensure mifepristone's benefits

[8] HHS Secretary Becerra recently issued a guidance document stating that a pharmacy's refusal to dispense mifepristone for miscarriage management due to its concern for abortion laws constituted unlawful sex discrimination (36).

for miscarriage management outweigh its risks. Furthermore, as described below, the misoprostol-only alternative has lower efficacy and similar risks but is not subject to an ETASU (or any REMS at all). As a result, the REMS burdens the equally safe and more effective miscarriage management protocol, making it harder for patients, especially poor and rural patients, to access it. Accordingly, a REMS with ETASU is inappropriate for a miscarriage management indication for mifepristone and should therefore be eliminated.

A. The Patient Agreement Form is Not Necessary for the Benefits of Mifepristone to Outweigh the Risks and Unduly Burdens Access to the Drug

We recommend that the Patient Agreement Form be removed entirely because it is medically unnecessary and repetitive of informed consent, as a previous review conducted by CDER determined in 2016.[9] As a result, the Form does nothing to ensure the benefits of the drug outweigh the risks. Moreover, for miscarriage management, there is an additional concern: the medical alternative (misoprostol alone) does not require patients to sign any form, and therefore the mandated Patient Agreement Form adds an administrative and logistical burden that disincentivizes the most effective protocol for medically managing miscarriage at the health systems level. It should therefore be removed for that reason.

If the Patient Agreement Form is retained, however, it at least minimally needs to be amended to reflect the new indication or separate forms should be used for the separate indications. The current Form makes people attest that they are ending a pregnancy, which is not accurate for the indication of miscarriage, in which the loss of the pregnancy has already occurred or is already in process. Asking a miscarriage patient to attest to having an abortion

[9] These recommendations were ultimately rejected by Dr. Janet Woodcock, who decided to retain this element of the REMS (37).

will confuse patients at best, but due to the prevalence of abortion stigma, it might also add emotional harm to their miscarriage experience (38).

B. The Provider Self-Certification Process for Mifepristone is Not Necessary for the Benefits of Mifepristone to Outweigh the Risks and Unduly Burdens Access to the Drug

Second, the Certified Provider Requirement serves no benefit to patient safety, especially in the miscarriage population. In this population, the pregnancy has already been confirmed and diagnosed as a miscarriage. Moreover, clinicians prescribing mifepristone for miscarriage know how to date a pregnancy, diagnose an ectopic pregnancy, and treat complications that arise (or refer to someone who could). Clinicians who commonly provide early pregnancy loss care, such as emergency medicine specialists, obstetrician-gynecologists, family physicians, women's health nurse practitioners, and certified nurse midwives, receive training in pregnancy dating, ectopic risk factors,[10] and care coordination (40,41). As a result, the certification is redundant and unnecessary to prove that mifepristone's benefits outweigh its risks for this indication.

The negligible or non-existent benefits of provider self-certification are vastly outweighed by the impediments to accessing mifepristone that result from this requirement. This requirement creates an administrative burden that discourages clinicians from using the drug. First, social science research demonstrates in other contexts that an opt-in requirement generally disincentivizes participation (42). The certification process therefore presents an administrative burden that busy clinicians may be unable or unwilling to fulfill without institutional support or technical assistance.

[10] Recent studies have suggested that mifepristone use is safe even for pregnancies of unknown location (PUL). In a 2022 retrospective cohort study of 432 abortion patients with a PUL and no ectopic risk factors, Goldberg and colleagues report that individuals had a faster time to rule out ectopic pregnancy when they were treated with mifepristone immediately, rather than delaying initiation of mifepristone until after pregnancy location was diagnosed (39).

In addition to the administrative burden, clinicians might also be particularly wary about undergoing the certification process for mifepristone given its relationship to abortion. Even before *Roe v. Wade* was overturned, abortion providers have consistently faced risks of violence and harassment unlike any other field of medicine (43). For that reason, clinicians might have reasonable reservations about opting into a prescription system that could, if their certification were leaked, suggest they were an abortion provider and open them up to violence and harassment (42). In recent qualitative studies in Illinois and Massachusetts, researchers found this fear was present even among physicians who personally only plan to prescribe mifepristone for miscarriage care (29,44). It is likely that clinicians' reservations will increase in states that have moved to ban abortion care since the *Dobbs* decision, further compounding the effects of abortion stigma (45). Research has shown that without certification, more clinicians would prescribe mifepristone. In qualitative studies in Massachusetts, Illinois, Alabama, and with a national sample, both generalist obstetrician-gynecologists and primary care providers described the REMS as a barrier to integration of mifepristone use in their practice (29,44,45,46).

The result is that only the limited number of clinicians who have already navigated mifepristone REMS compliance to provide abortion care are prepared to prescribe mifepristone for miscarriage. And those clinicians are almost always located in cities (47,48), meaning that rural residents will disproportionately lack access to certified providers who can prescribe mifepristone as part of a medical miscarriage protocol. Moreover, rural residents are more likely to lack access to OBGYNs (21), meaning that surgical management is also less likely to be an option. Thus, rural residents will only have access to a less effective medical protocol for managing miscarriage or may be forced to complete their miscarriage without active measures.

This certification barrier has devastating effects for the miscarriage population, who may only be able to access the most effective medical miscarriage management protocol if their hospital or provider group has an abortion provider on staff. And these burdens fall disproportionately on poor and rural women, contrary to goals of the REMS statute. Because the misoprostol-only alternative does not require certification despite being less effective and having a similar risk and safety profile, the certified provider requirement again burdens the more effective protocol and makes it much harder to access the best medical treatment for miscarriage.

C. *The Certified Pharmacy Requirement is Not Necessary for the Benefits of Mifepristone to Outweigh the Risks and Unduly Burdens Access to the Drug*

Though the details of the new pharmacy certification requirement have yet to be finalized, research also suggests that the pharmacy requirement is unnecessary to ensure that mifepristone's benefits outweigh its risks and unduly burden access. A preliminary trial of pharmacy dispensing of mifepristone conducted by Grossman and colleagues in California and Washington state suggests that pharmacies are already equipped to dispense the drug without special certification. In this trial of 266 individuals, which was halted early due to the COVID-19 pandemic, rates of non-serious adverse events following pharmacy dispensing were extremely low (1.5%) and no higher than rates from studies of in-clinic dispensing, and satisfaction was high, with 65.4% of patients very and 19% somewhat satisfied. Though the pharmacies in this study partnered with prescribers, there is no reason to think the results would be different with retail pharmacies, especially in light of the Canadian data discussed in the next section (49).

The pharmacy certification requirement is also expected to create similar barriers to care for the miscarriage population as the provider certification. The extra administrative burden will disincentivize participation and the fact that pharmacies are businesses, not people, exacerbates this concern. Unlike clinicians, who may endure the obstacles of certification out of a moral conviction or professional obligation to provide the best reproductive healthcare, pharmacies will engage in a business decision where they will evaluate whether the financial gain in distributing the drug is worth the costs and risks (42). Moreover, given that the antiabortion movement is known for boycotts, pharmacies will also likely weigh the risks associated with their status as a certified pharmacy becoming public. Walgreens already indicated that it will not seek certification, and many large retail pharmacies may follow suit (42). People will therefore be dependent on online pharmacies to access mifepristone—even for miscarriage management.

As with the certified provider requirement, the burdens associated with the certified pharmacy requirement will also fall disproportionately on poor and rural women, contrary to the REMS statute. Most Americans rely on neighborhood retail pharmacies to obtain their prescription drugs, and retail pharmacy distribution of drugs can increase access for rural residents (42). For instance, when the government in Australia started allowing retail pharmacies to dispense mifepristone, access to the drug increased, especially in rural areas (43). If only online pharmacies become certified to dispense mifepristone, then it might harm those with less digital literacy, who may have more difficulty interfacing with online pharmacies after their clinicians prescribe mifepristone for miscarriage. This might be especially true for patients struggling to process their loss, who have little emotional capacity to set up an account and learn a new pharmacy's online interface. Moreover, adults who are not digitally literate are disproportionately less educated and more likely to be Black, Hispanic, or foreign born, meaning

that these groups would likely be the most adversely impacted if mifepristone is available solely through online pharmacies (50). Given that the misoprostol-only alternative can be accessed at any pharmacy, the pharmacy certification requirement therefore incentivizes the less effective protocol for medical miscarriage management and will limit access to the most effective protocol.

D. Existing Data Demonstrate that a Removal of All REMS Requirements Will Not Harm Patient Safety

After Canada removed all restrictions on prescribing mifepristone for abortion, thereby allowing it to be prescribed and dispensed like any other drug ("normal prescribing"), there was no increase in complications from mifepristone use (51). In a 2022 study, Schummers and colleagues used multiple sources of medical and administrative data to create a linked dataset containing information on Ontario residents receiving abortion care through Canada's universal, single-payer health system from 2012 through 2020 (total n=314,859 abortions). They found no difference in the rate of any complication (0.67% vs. 0.69%) or in the rate of serious adverse events (0.03% vs. 0.04%) between the ten-month period when mifepristone was distributed with REMS-like restrictions and the twenty-eight-month period of normal prescribing after all such restrictions were lifted and mifepristone was prescribed with no special self-certification and dispensed routinely from pharmacies (52). We expect the same results in the miscarriage population given the similarity in regimens when using mifepristone for abortion and miscarriage.

III. FDA Should Immediately State That it Will Exercise Enforcement Discretion Until This Process is Completed

As just discussed, clinicians who treat miscarriage and their patients have an urgent need to address increasing barriers to accessing mifepristone. While we urge both FDA and Danco to act expeditiously on our requests, we recognize that submission and review of an sNDA and corresponding REMS changes will take time. Thousands of patients suffering miscarriages will be adversely affected during this period. We therefore request that FDA immediately announce that it will exercise enforcement discretion to permit the use and distribution of mifepristone consistent with the requested miscarriage indication and changes in the REMS for this indication. The public health needs for this safe and effective treatment are substantial. Just last year, FDA exercised enforcement discretion with respect to certain pharmacy and wholesale distribution requirements under the Clozapine REMS because they had frustrated patients' ability to access a needed drug. FDA explained that its "highest priorities" are "[c]ontinuity of care, patient access . . ., and patient safety" (2). Patient access to the gold standard of miscarriage care, which is being significantly restricted due to the mifepristone REMS, and patient safety weigh heavily in favor of exercising enforcement discretion here as well. There is, of course, precedent for FDA to exercise enforcement discretion specifically with respect to the mifepristone REMS as well, as it did last year during the COVID-19 public health emergency (3). Enforcement discretion will ensure patients have access to the most effective regimen for miscarriage management while Danco submits, and FDA reviews, the sNDA.

ENVIRONMENTAL IMPACT

The proposed action is exempt from the requirement of an environmental impact statement under 21 C.F.R. § 25.24(c)(2).

ECONOMIC IMPACT

No information required at this time.

CERTIFICATION

The petitioners certify that, to the best of our knowledge and belief, this petition includes all information and views on which the petition relies. The petitioners know of no data unfavorable to the opinion.

Signed:

American College of Obstetricians and Gynecologists
Advancing New Standards in Reproductive Health
All Families Healthcare
American Academy of Family Physicians
American Civil Liberties Union
American College of Nurse-Midwives
American Humanist Association
American Medical Association
American Medical Women's Association
American Society for Reproductive Medicine
Association of Women's Health, Obstetric and Neonatal Nurses
Black Mamas Matter Alliance
Centering Equity, Race, and Cultural Literacy in Family Planning
Center for Reproductive Rights
Collective Energy for Nurturing Training in Reproductive and Sexual Health
Community Catalyst
Doctors for America FDA Task Force
EMAA Project
ExPAND Mifepristone
Guttmacher Institute
Gynuity Health Projects
Ibis Reproductive Health
Ipas
Jacobs Institute of Women's Health
Jefferson Health
Just The Pill/Abortion Delivered
NARAL Pro-Choice America
National Abortion Federation
National Association of Nurse Practitioners in Women’s Health
National Birth Equity Collaborative

National Consumers League
National Family Planning & Reproductive Health Association
National Health Law Program
National Latina Institute for Reproductive Justice
National Partnership for Women & Families
National Women's Health Network
Nurses for Sexual and Reproductive Health
Partners in Abortion Care
Pegasus Health Justice Center
Physicians for Reproductive Health
Planned Parenthood Federation of America
Power to Decide
Reproductive Health Access Project
Reproductive Health Education in Family Medicine
SisterReach
Society for Academic Specialists in General Obstetrics and Gynecology
Society for Maternal-Fetal Medicine
Society of Family Planning
UCSF Bixby Center for Global Reproductive Health

References

1. Department of Health and Human Services. Prescription drug products; certain combined oral contraceptives for use as postcoital emergency contraception. Notice. 62 Fed. Regis. 1997 February 25; 8610.
2. U.S. Food and Drug Administration. FDA is temporarily exercising enforcement discretion with respect to certain Clozapine REMS program requirements to ensure continuity of care for patients taking clozapine [Internet]. 2021 December 2. Available from: https://www.fda.gov/drugs/drug-safety-and-availability/fda-

temporarily-exercising-enforcement-discretion-respect-certain-clozapine-rems-program

3. Woodcock J. (Acting Commissioner, U.S. Food and Drug Administration, Silver Spring, MD). Letter to: Phipps M. (Chief Executive Officer, American College of Obstetricians and Gynecologists, Washington, D.C.). Grobman W. (President, Society for Maternal-Fetal Medicine, Washington, D.C.). 2021 April 12. Available from: https://www.aclu.org/letter/fda-response-acog-april-2021
4. Becerra J. Remarks by Secretary Xavier Becerra at the press conference in response to President Biden's directive following overturning of Roe v. Wade [Speech video recording]. 2022 June 28. U.S. Department of Health and Human Services. Available from: https://www.hhs.gov/about/news/2022/06/28/remarks-by-secretary-xavier-becerra-at-the-press-conference-in-response-to-president-bidens-directive-following-overturning-of-roe-v-wade.html
5. American College of Obstetricians and Gynecology. Committee on Practice Bulletins–Gynecology. Early pregnancy loss: interim update. Obstetrics and Gynecology, 2018 Nov;132(5):e197-207.
6. Centers for Disease Control and Prevention. Pregnancy and infant loss [Internet.] 2020 August 13 [cited 2022 July 20]. Available from: https://www.cdc.gov/ncbddd/stillbirth/features/pregnancy-infant-loss.html
7. Quenby S, Gallos ID, Dhillon-Smith RK, Podesek M, Stephenson MD, et al. Miscarriage matters: the epidemiological, physical, psychological, and economic costs of early pregnancy loss. Lancet. 2021; 397: 1658–67.

8. Wang X, Chen C, Wang L, Chen D, Guang W, French J. Conception, early pregnancy loss, and time to clinical pregnancy: a population-based prospective study. Fertil Steril. 2003;79(3):577-84.
9. Tessum CW, Paolella DA, Chambliss S, Apte JS, Hill JD, Marshall, JD. PM2. 5 polluters disproportionately and systemically affect people of color in the United States. Science Advances. 2021; 7(18):eabf4491.
10. Kaiser Family Foundation. State health facts: poverty rate by race/ethnicity, 2019. [Internet.] 2022 [cited 2022 August 7]. Available from: https://www.kff.org/other/state-indicator/poverty-rate-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D
11. Shorter JM, Koelper N, Sonalkar S, Oquendo MA, Sammel MD, Schreiber CA. Racial disparities in mental health outcomes among women with early pregnancy loss. Obstet Gynecol. 2021;137(1):156-163.
12. Layne L. "True gifts from God": paradoxes of motherhood, sacrifice, and enrichment in motherhood lost: a feminist account of pregnancy loss in America. Routledge, 2002:145-172.
13. Wallace RR, Goodman S, Freedman LR, Dalton VK, Harris LH. Counseling women with early pregnancy failure: utilizing evidence, preserving preference. Patient Educ Couns. 2010;81(3):454-61.
14. Goldberg AB, Carusi D, Westhoff C. "Pregnancy Loss." In Paul M, Lichtenberg PES, Borgotta L, Grimes DA, Stubblefield PG, Creinin MD, eds. Management of

Unintended and Abnormal Pregnancy: Comprehensive Abortion Care. Wiley, 2009, pp. 264-279.

15. Trinder J, Brocklehurst P, Porter R, Read M, Vyas S, Smith L. Management of miscarriage: expectant, medical, or surgical? Results of randomised controlled trial (miscarriage treatment (MIST) trial). BMJ. 2006 May 27; 332(7552):1235-40.
16. Blohm F, Fridén BE, Milsom I, Platz-Christensen JJ, Nielsen S. A randomised double blind trial comparing misoprostol or placebo in the management of early miscarriage. BJOG. 2005 Aug;112(8):1090-1095.
17. Zhang J, Gilles JM, Barnhart K, Creinin MD, Westhoff C, Frederick MM. A comparison of medical management with misoprostol and surgical management for early pregnancy failure. N Engl J Med. 2005 Aug 25;353:761-769
18. Wieringa-de Waard M, Bindels PJE, JVos J, Bonsel GJ, Stalmeier PFM, Ankum WM. Patient preferences for expectant management vs. surgical evacuation in first-trimester uncomplicated miscarriage. J Clin Epidemiol. 2004 Feb;57(2):167-73.
19. Wallace R, DiLaura A, Dehlendorf C. "Every person's just different": women's experiences with counseling for early pregnancy loss management. Womens Health Issues. 2017;27(4):456-462.
20. Ho PC. Women's perceptions on Medical Abortion. Contraception. 2006 Jul;74(1):11-5.
21. Rayburn WF, Klagholz JC, Murray-Krezan C, Dowell LE, Strunk AL. Distribution of American Congress of Obstetricians and Gynecologists fellows

and junior fellows in practice in the United States. Obstet Gynecol. 2012;119(5):1017-1022.

22. Agency for Healthcare Research and Quality. Primary care workforce facts and stats number 3: Pub. No. 12-P001-4-EF [Internet.]. 2021 Jan [cited 2022 Aug 7]. Available from: https://www.ahrq.gov/sites/default/files/publications/files/pcwork3.pdf
23. Schreiber CA, Creinin MD, Atrio J, Sonalkar S, Ratcliffe SJ, Barnhart KT. Mifepristone pretreatment for the medical management of early pregnancy loss. N Engl J Med 2018;378:2161-70.
24. Chu JJ, Devall AJ, Beeson LE, Hardy P, Cheed V, et al. Mifepristone and misoprostol versus misoprostol alone for the management of missed miscarriage (MifeMiso): a randomised, double-blind, placebo-controlled trial. Lancet. 2020; 396(10253): 770–778.
25. Neilson JP, Hickey M, Vazquez JC. Medical treatment for early fetal death (less than 24 weeks). Cochrane Database Syst Rev. 2006 Jul 19;2006(3):CD002253.
26. Kim C, Barnard S, Neilson JP, Hickey M, Vazquez JC, Dou L. Medical treatments for incomplete miscarriage. Cochrane Database Syst Rev. 2017 Jan 31;1(1):CD007223.
27. Beaman J, Prifti C, Schwarz EB, Sobota M. Medication to manage abortion and miscarriage. J Gen Intern Med. 2020;35(8):2398–405
28. Ghosh J, Papadopoulou A, Devall AJ, Jeffery HC, Beeson LE, et al. Methods for managing miscarriage: a network meta-analysis. Cochrane Database Syst Rev. 2021 Jun 1;6(6):CD012602.

29. Neill S, Goldberg AB, Janiak E. Medication management of early pregnancy loss: the impact of the US Food and Drug Administration Risk Evaluation and Mitigation Strategy [A289]. Obstet Gynecol. 2022 May;139: 83S.

30. Alabama Chemical Abortion Prohibition Act, H.B. 261, Reg. Sess. (Alabama 2022).

31. Unlawful Abortion Medication, HB 2811, Reg. Sess. (Arizona 2022). https://apps.azleg.gov/BillStatus/BillOverview/77880

32. Belluck, P. They had miscarriages, and new abortion laws obstructed treatment [Internet]. The New York Times. 2022 July 17 [cited 2022 July 20]. Available from: https://www.nytimes.com/2022/07/17/health/abortion-miscarriage-treatment.html

33. Murphy T. CVS seeks verification on drugs with possible abortion use [Internet]. AP News. 2022 July 21 [cited 2022 July 21]. Available from: https://apnews.com/article/abortion-us-supreme-court-health-medication-1f2e8da6ac0ff43e0128c683f40689db

34. Sellers F, Nirappil F. Confusion post-Roe spurs delays, denials for some lifesaving pregnancy care [Internet]. The Washington Post. 2022 July 16 [cited 2022 July 20]. Available from: https://www.washingtonpost.com/health/2022/07/16/abortion-miscarriage-ectopic-pregnancy-care/

35. Christensen J. Women with chronic conditions struggle to find medications after abortion laws limit access [Internet]. CNN. 2022 July 22 [cited 2022 July 22].

Available from: https://www.cnn.com/2022/07/22/health/abortion-law-medications-methotrexate/index.html

36. U.S. Department of Health and Human Services. Office for Civil Rights. Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services. 2022 July 13. Available from: https://www.hhs.gov/sites/default/files/pharmacies-guidance.pdf
37. U.S. Food and Drug Administration. Center for Drug Evaluation and Research. Risk Assessment and Risk Mitigation Review(s); Application Number 020687Orig1s020. 2016 March 29. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/ da/2016/0 20687Orig1s020RiskR.pdf
38. Norris A, Bessett D, Steinberg JR, Kavanaugh ML, De Zodro S, Becker D. Abortion stigma: a reconceptualization of constituents, causes, and consequences. Women's Health Issues. 2011; 21(3 Suppl):S49-54.
39. Goldberg AB, Fulcher IR, Fortin J, Hofer RK, Cottrill A, Dthier D, et al. Mifepristone and misoprostol for undesired pregnancy of unknown location. Obstet Gynecol 2022;139(5):771-780.
40. Society of Teachers of Family Medicine. [Internet.] EPAs, competencies, subcompetencies, and milestones. Accessed June 17, 2022. Available from: https://www.stfm.org/teachingresources/resources/epascompetenciesmilestones/overview/#7136

41. Accreditation Council for Graduate Medical Education. Obstetrics and Gynecology Milestones. 2021. [cited 2022 September 13.] Available from: https://www.acgme.org/globalassets/pdfs/milestones/obstetricsandgynecologymilestones.pdf

42. Donley G. Medication abortion exceptionalism. Cornell Law Review. 2022;107. U. of Pittsburgh Legal Studies Research Paper No. 2021-09. Posted: 5 Mar 2021 Last revised: 7 Jul 2022.

43. Cohen DS, Connon K. Living in the crosshairs: The untold stories of anti-abortion terrorism. Oxford University Press; 2015.

44. Calloway D, Stulberg DB, Janiak E. Mifepristone restrictions and primary care: Breaking the cycle of stigma through a learning collaborative model in the United States. Contraception. 2021 July; 104(1):24-28.

45. Mokashi M, Boulineaux C, Janiak E, Boozer M, Neill S. "There's only one use for it": stigma as a barrier to mifepristone use for early pregnancy loss in Alabama. [A31]. Obstet Gynecol. 2022 May:139:9S-10S.

46. Razon N, Wulf S, Perez C, McNeil S, Maldonado L, et al. Exploring the impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the integration of medication abortion into US family medicine primary care clinics. Contraception 2022;109(5):19-24.

47. Bearak JM, Burke KL, Jones RK. Disparities and change over time in distance women would need to travel to have an abortion in the USA: a spatial analysis. Lancet Public Health. 2017; 2:e493–500.

48. Committee on Health Care for Underserved Women. Health Disparities in Rural Women. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2014;123:384-388.

49. Grossman D, Baba CF, Kaller S, Biggs MA, Raifman S, et al. Medication abortion with pharmacist dispensing of mifepristone. Obstet Gynecol 2021;137(4):613-622

50. Mamedova S, Pawlowksi E. A Description of U.S. adults who are not digitally literate. National Center for Education Statistics. 2018 May 29. Available from: https://nces.ed.gov/pubsearch/pubsinfo.asp?pubid=2018161

51. Health Canada. Regulatory decision summary — Mifegymiso — Health Canada [Internet]. 2017 November 7. Available from: https://hprrps.hres.ca/reg-content/regulatory-decision-summary-detail.php?lang= en&linkID=RDS00294

52. Schummers L, Darling EK, Dunn S, McGrail K, Gayowsky A, et al. Abortion Safety and Use with Normally Prescribed Mifepristone in Canada. N Engl J Med. 2022 Jan 6;386(1):57-67.

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]

***

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.

Exhibit C

APPENDIX

TABLE OF CONTENTS

EXHIBIT 1

Declaration of Graham T. Chelius, M.D.

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN**
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*
***admission for pro hac vice pending*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE**
RUTH HARLOW**
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN**
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]

DECLARATION OF GRAHAM T. CHELIUS, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Graham T. Chelius, M.D., declares and states as follows:

1. I make this declaration based on my own personal knowledge and if called to testify I could and would do so competently as follows.

2. I am a plaintiff in the above-captioned litigation, which challenges the U.S. Food and Drug Administration's Risk Evaluation and Mitigation Strategy ("REMS") for Mifeprex. I provide this declaration in support of that litigation. I do so in my individual capacity, and not on behalf of any entity with which I am associated or where I practice, including my employer, Hawaii Health Systems Corporation.

3. I am a board-certified Family Medicine physician based on the island of Kaua'i in Hawai'i. I practice medicine at Kauai Veterans Memorial Hospital ("Kauai Veterans") and its associated clinics, West Kauai Clinics. Kauai Veterans is located on the western side of the island in the town of Waimea, Kaua'i. Kauai Veterans currently employs about 275 people.

4. I am currently the Chief of Staff at Kauai Veterans, a position I have held since February 2018. Immediately before that, and after serving for several years as a board member, I served as the Chief Medical Officer for the Hawaii Health Systems Corporation's Kaua'i Region (which, in addition to Kauai Veterans, included Samuel Mahelona Memorial Hospital, on the eastern side of the

island in Kapa‘a, Kaua‘i), but resigned from that position in December 2017 in favor of this new opportunity as Chief of Staff. In my role as Chief Medical Officer, I was primarily responsible for managing the relationship between Hawaii Health Systems Corporation and the physicians who serve the Kaua‘i region, including participating in contract negotiations, overseeing physician staffing assignments, and responding to any complaints brought against physicians by both patients and staff. As Chief of Staff, I have very similar responsibilities, but rather than acting as a representative of the administration I am an elected representative of the physicians who form the medical staff. Both my current and former positions require that I be involved in resolving most conflicts that arise among the small clinical team at Kauai Veterans.

5. I received my medical degree from the University of Wisconsin in 2001, and completed my residency in Family Medicine at North Colorado Medical Center. Since January 2009, I have been practicing medicine in Hawai‘i at Kauai Veterans.

6. In my current role as Chief of Staff, I continue to treat patients. Within my specialty of Family Medicine, I focus in particular on women’s health, including obstetrics, and on chemical dependency treatment.

7. During the twelve years that I have been practicing medicine in Hawai‘i, I would estimate that I have cared for more than 2,750 pregnant patients

and delivered over 1,100 babies on the island of Kaua‘i. While many of my patients have much-wanted pregnancies, a substantial percentage choose to end their pregnancies, and come to me seeking abortion care. Most of these patients are medically eligible for the FDA-approved medication abortion regimen: Mifeprex followed by the drug misoprostol.

8. However, I am unable to prescribe Mifeprex to patients who need this medication because, as detailed below, complying with the requirements in the REMS that I procure, stock, and dispense Mifeprex at my health care facility—rather than issuing a prescription, from the privacy of my office, for my patient to fill at a pharmacy—would damage my professional standing locally, disrupt the workplace dynamics I am responsible for maintaining, interfere with my ability to continue to serve the many patients I now serve, and jeopardize my patients' confidentiality. The Mifeprex REMS deters clinicians and harms patients by imposing unique, unnecessary, and onerous requirements on their care. Put plainly, the REMS impedes my and other clinicians' ability to safely and appropriately care for our abortion and miscarriage patients as we would patients seeking any other service.

9. The distribution restriction substantially interferes with my ability to practice medicine in accordance with my professional judgment. Because of the Mifeprex REMS, I am unable to provide medication abortions to my patients, even

in situations when my best medical judgment would strongly counsel in favor of providing this care.

10. There is only a narrow window in which a patient can take the Mifeprex-misoprostol regimen for early pregnancy termination: this method has been approved by FDA only for the first ten weeks of pregnancy, and that is the period during which clinicians generally prescribe it. But patients cannot know they are pregnant until four weeks, and many patients do not realize they are pregnant until their sixth to eighth week. By the time a patient sees me, they typically have only a few weeks—indeed, often only a few days—in which to take the medications. If they cannot access Mifeprex within the window of availability, the only option is a surgical abortion. Nevertheless, because of the REMS, I am unable to provide medication abortion care in these time-sensitive situations.

11. There are no abortion providers on Kaua‘i, a federally designated "medically underserved area." The closest provider of abortion services is on O‘ahu, which can be reached only by airplane. I have seen the anxiety and confusion in my patients' eyes when I tell them that they have to fly to O‘ahu to obtain an abortion. I have heard them describe their frustration, anger, and heartbreak. For some patients—many of whom are already experiencing significant anxiety as a result of the unwanted pregnancy, and some of whom are also struggling with the challenges and trauma of poverty, drug addiction,

joblessness, and/or domestic violence—this news is simply devastating.

12. Traveling to O‘ahu for a surgical abortion costs my patients money and time, and causes them stress. Many are forced to make significant personal and financial sacrifices in order to get the health care they need. They must find the money to pay, or if possible make arrangements for insurance to pay, for the costs of transportation to and from the airports on both islands, and for the flights themselves. They must arrange to take time off from work or school, and arrange for child care if they have children, which most do. If a loved one is accompanying them to O‘ahu for support, that person must bear these costs as well. This travel and related logistics also impose significant psychological and emotional strain on many of my patients, and in my experience can be especially hard on young women, women struggling with substance abuse, women for whom English is not their first language, and women who are homeless.

13. Raising the money and making arrangements to travel is often time-consuming. Given the circumstances of my patients’ lives, it is not uncommon for it to take several weeks, a month, or longer. Indeed, even for those of my patients fortunate enough to have insurance coverage for the abortion procedure and the travel to obtain it (though, of course, still not for child care, missed work, or food away from home), it typically takes one to two weeks just for the paperwork to be approved. As previously noted, delays often mean that patients are no longer

eligible for medication abortion at all, and instead must have a surgical procedure. Moreover, while abortion is very safe, the risks increase as pregnancy advances. And, on top of that, patients whose abortions are delayed also face health risks associated with continuing a pregnancy for additional days, weeks, or months. For such patients, delaying their abortion means they are sicker, longer.

14. I recall one patient whose experience powerfully illustrates many of the harms caused and burdens created by the REMS. She is a woman whom I had been treating for substance use disorder and who had previously seen us for obstetrical care for her first child. She came to my office seeking an abortion prior to 10 weeks of pregnancy. After evaluating her, I concurred that a medication abortion was an appropriate treatment, that she could utilize the Mifeprex-misoprostol regimen, and that she should do so without delay. I wanted to—and would have—provided her with the medication abortion she desired if I could have written a prescription for Mifeprex for her to fill at a pharmacy. But, because of the REMS, I could not provide that care to my patient. Instead, she was forced to travel to O‘ahu.

15. Because of the complications in this woman’s life, by the time she was finally able to make the journey to O‘ahu, more than six weeks had passed. At that point, she had to have a two-day dilation and evacuation (“D&E”) abortion instead of the medication abortion she had wanted. Not only is D&E a significantly

more complex and invasive procedure, but it also required her to bear the costs of staying on O‘ahu—in a hotel, away from her home and her family—overnight. This was utterly unaffordable for her. Indeed, I understand that she called her sister on the day of her first appointment to tell her that she was on O‘ahu for an abortion and had only $20 in her pocket. Her sister jumped on the plane to help my patient find lodging and provide her with emotional support during the procedure—which of course meant that my patient’s sister also had to bear the costs of a round-trip flight, hotel, and food during her stay. Fortunately, her sister managed to drop everything and come to her aid, but otherwise I don’t know how she would have managed to get to and from her appointments or where she would have stayed overnight.

16. I still feel frustrated and upset that my patient and her family had to bear the emotional trauma, financial burdens, and medical risks of this experience. And she is far from the only patient I have had who was eligible for medication abortion at the time I saw her, but ultimately had to not only fly to O‘ahu to get the care they needed, but by the time they did so were too late for a medication abortion and had to have a procedure instead. Again, none of this would be necessary if I could have simply written this patient, and other patients like her, a prescription for Mifeprex when she was in my office early in her pregnancy.

17. While that patient *was* ultimately able to get an abortion—not all of my patients are. In some cases, the travel burdens created by the Mifeprex REMS are simply untenable, and my patients end up carrying pregnancies to term and having children against their will. For instance, one patient who struggles with chemical dependency never was able to get to O‘ahu, despite her expressed desire for an abortion and despite extensive assistance with the travel arrangements. As a result, she was forced to carry the pregnancy to term (and her child was exposed to drugs throughout the entire pregnancy). I have continued to care for such patients through the course of their pregnancies and beyond, and have seen firsthand the emotional, physical, and financial burdens that an unwanted pregnancy can cause.

18. Sadly, the situation is even worse for women who live on Ni‘ihau, which is a sparsely populated island just west of Kaua‘i. There are no paved roads, and no cell coverage—let alone health care—on Ni‘ihau. Because of the lack of access to reproductive health care on-island, women on Ni‘ihau have to schedule transportation by boat to Kaua‘i just to see a doctor. My hospital delivers virtually all the babies for pregnant women on Ni‘ihau. If a woman on Ni‘ihau wants to terminate her pregnancy, the obstacles are even greater for her than for a woman on Kaua‘i. But if the REMS did not exist, she could simply go to Kaua‘i to obtain Mifeprex the same day, instead of going to Kaua‘i only to then get referred to an O‘ahu-based abortion provider and facing all the associated obstacles. I mention

Ni‘ihau just to show how burdens can aggregate and compound into an entirely insurmountable barrier to accessing safe abortion care.

19. I became a doctor to make my patients’ lives easier, less painful, and more fulfilling. But, because of the REMS, I must watch them suffer medical, emotional, and financial burdens when I cannot provide them with the abortion care that they desire. In addition, as a physician, I am concerned about continuity of care—yet the restrictions imposed by the Mifeprex REMS mean that I must needlessly hand off my patients to someone else for care, breaking that continuity for absolutely no medical reason. While I am confident that the providers to whom I refer my patients in O‘ahu provide high-quality care, it pains me to have to turn my patients away and send them off island to get care they need and that I am perfectly competent to provide. The Mifeprex REMS thus prevents me from providing uninterrupted, comprehensive primary health care to my patients, as I strive to do whenever possible. It violates my fundamental beliefs as a health care provider to have to deny a patient’s request for time-sensitive, medically indicated care only because of medically unjustified restrictions like the Mifeprex REMS.

20. For the past several years, some of my patients have been able to avoid most of these burdens by participating in the Telemedicine Abortion Study (“TelAbortion”), which is run through the University of Hawai‘i. This study—which I understand operates as a temporary waiver of the REMS—allows certain

qualifying patients to receive Mifeprex by overnight mail from the study's principal investigators on O'ahu without having to fly to that island for care. Recognizing how difficult the journey to O'ahu is for many of my patients, wherever possible, I have assisted them in participating in the study. I believe this model of care delivery—mailing Mifeprex following a telemedicine visit—is safe and effective and a valuable option for my patients.

21. But the TelAbortion study's process carries its own burdens and complexities, and therefore excludes the most vulnerable, highest-risk patients. The cost of participation in TelAbortion presents the first hurdle. While the State of Hawai'i generally covers the cost of abortion services through its Medicaid program, it does not cover the cost of Mifeprex obtained through the TelAbortion study. Thus, Medicaid enrollees must pay out-of-pocket for Mifeprex provided through the study. This effectively excludes or deters many lower-income patients from participating.

22. The logistics are another hurdle. In most cases, the study protocols require that a participating patient first have a blood test and ultrasound performed, and then mail, fax, or email the results to a physician at the University of Hawai'i. Then, that physician must connect with the patient by secure videoconference at a set appointment time. Some of my patients—including some who are homeless, poor, or live in extremely remote parts of Kaua'i—do not have reliable internet or

cell phone service, access to technology with secure videoconferencing capability, or the ability to use this technology in a private space where they can speak confidentially. In such cases, I often have to step in to help them. On several occasions, I have stayed late at my office to let a patient use my computer to participate in the study, but this is not always possible: my patients' schedule, my schedule, and the schedule of the physicians on O'ahu do not always align, and certainly do not always align before the patient's window for a medication abortion closes. Helping my patients participate in the TelAbortion study has taken, and continues to take, many hours of my time—and even so, some of my patients still cannot successfully use it.

23. A third hurdle is that participating patients must have a physical address to which a package can be securely and confidentially mailed. But my patients who are homeless do not have such a safe address. So the study also cannot provide relief to such patients.

24. For all patients, even if they can gather the resources to participate in TelAbortion, the processes and requirements of participating in a research study delay care. I have on numerous occasions seen patients who were still within the window for a medication abortion, but did not have enough time to access it through the study.

25. Critically, I understand that the TelAbortion study is only temporary. When it ends, it will no longer exist as an option for me and my patients.

26. The harms and burdens I have described that both my patients and I are experiencing flow directly from my inability to issue a prescription for Mifeprex to be filled at a pharmacy or by mail order as I can do with countless other equally or less safe drugs. Most of these harms and burdens would be entirely eliminated, or substantially reduced, if the REMS were eliminated.

27. In addition, the REMS imposes a broader set of harms by deterring and blocking qualified clinicians from becoming medication abortion providers through its unique and unnecessary barriers. First, in order to comply with the requirement in the REMS that I procure, stock, and dispense Mifeprex at my medical facility, I would have to risk serious damage to my professional standing in my workplace and to my respected role in the local community. Abortion is an issue about which people hold very strong views, and some of my colleagues and staff members strongly oppose it. In my tight-knit workplace, attempting to establish a policy for procuring, stocking, and dispensing Mifeprex at our facility would create internal conflict, undermining the team cohesion that I am responsible for developing and maintaining as Chief of Staff. It would also jeopardize my ability to continue in that elected position, threaten initiatives I am undertaking to improve care within our hospital system, and reduce the time I have

to treat patients. I cannot afford these personal and professional risks.

28. To be clear, many of my colleagues and staff already know that I provide abortion referrals. I know that some staff oppose even this; some have directly expressed such views to me. But if I were to comply with the Mifeprex REMS, I would be doing more than just supporting access to abortion in my *individual* professional capacity—I would also have to involve, and win the approval of, multiple colleagues and staff members in the process of procuring, stocking, dispensing, and billing for Mifeprex within our health care facility. Asking or demanding that my colleagues who have deeply held views against abortion participate or assist in providing abortions would cause significant conflict among my staff—conflict that, as Chief of Staff, I would also be required to manage, if possible. The negative consequences for my professional standing and for carefully nurtured workplace dynamics, which benefit all of our patients, deter me from attempting to comply with the Mifeprex REMS.

29. Relatedly, I also have had serious personal safety concerns about the requirement in the REMS that I register with the drug manufacturer and drug distribution company as an abortion provider. I understand that they must keep confidential the list of clinicians registered to prescribe Mifeprex. But particularly in light of the many recent health care hacking incidents, I have been concerned about being inadvertently or maliciously exposed as an abortion provider, and the

resulting likelihood of public backlash to me and my family.

30. Of course, my name is now public in the context of this litigation, and my experience since filing this lawsuit has validated my earlier concerns. Since the lawsuit was filed, I have received numerous phone calls and letters from strangers relating to this litigation. Many of those communications were positive and supportive. But a few were negative and concerning. Based on security consultations, I now carefully examine envelopes for toxic material, and have tried to remember to only open packages that I have been expecting. We also installed a security system at our house. In a country where abortion clinic shootings are commonplace and abortion providers have been assassinated, I have feared risking my and my family's safety by following through with what the Mifeprex REMS requires.

31. I ultimately made the difficult choice to publicize my desire to provide abortion care through this lawsuit, because I believe this case has the potential to expand access to medication abortion for patients all across the country. My family and I felt that this goal was worth the risk to our safety and privacy. But we did not make that choice lightly, and I expect that I am not the only physician who has found the REMS requirement that I add my name to a list of all medication abortion providers in the country a serious deterrent to providing this care.

32. I am also concerned that compliance with the Mifeprex REMS would jeopardize my patients' privacy. By requiring that my facility be responsible for the purchasing, stocking, dispensing, and billing of Mifeprex—discrete responsibilities held by discrete members of our staff—the REMS injects many more people into the abortion care process. This raises real confidentiality concerns in the small-town community in which I practice. Everybody knows you and you know everybody in Waimea, a town of fewer than 2,000 people on an island of just over 65,000. In fact, it is not uncommon for members of my staff to bump into my patients at the grocery store, gym, or on the street. For myself, going to either of the two grocery stores in Waimea is a social event due to the fact that I will certainly know someone either working or shopping at the store.

33. Additionally, many members of the community have a family member, friend, or neighbor employed at Kauai Veterans, and, as a result, members of our community are sometimes nervous about seeking intimate medical care from us out of fear for their confidentiality. Certain elements of a person's medical history (history of abortion, sexually transmitted diseases such as HIV or gonorrhea, a history of rape, struggles with substance use disorder) are closely guarded by patients due to real or perceived stigma from those in the general population and medical providers.

34. For instance, I have a patient who, while pregnant, asked that a specific doctor not be involved in her care because she was afraid that the provider might divulge her medical history to family members of the doctor whom the patient also knew. Fortunately, I was able to sufficiently reassure this patient that I trust this physician to respect her confidentiality, which resulted in this patient continuing to receive care from us. But there is no doubt that, in our community, patients struggle with the decision of whether to get adequate medical care due to concerns about their confidentiality. And, indeed, it would be entirely reasonable for a patient to fear for the privacy of her abortion decision if she happens to know, for instance, some of the numerous people who may be involved with the billing, ordering, recording, and physical dispensing of medication at our facility (which, again, is a perfectly plausible scenario in our small town).

35. By contrast, if the Mifeprex REMS did not exist, I would be able to write a prescription for Mifeprex for my patient without needing to let anyone else know about the prescription except, at most, the patient's nurse, a medical records clerk, and the patient's trusted pharmacist (or a pharmacy on the other side of the island, or a mail-order pharmacy, if that is the patient's preference). The risk to my patients' confidentiality is thus substantially higher under the Mifeprex REMS.

36. The Mifeprex REMS also presents significant logistical hurdles. In order to stock and dispense Mifeprex onsite, I would need to first get a policy created for storing and dispensing the drug in the clinic, and then secure approval from the Pharmacy and Therapeutics committee at Kauai Veterans. I would also need to complete and submit all of the paperwork associated with becoming a certified prescriber under the Mifeprex REMS and setting up an account with the drug distribution company—a process that would take even more time and effort because the purchasing agreement would need to go through our contracting office, which has to follow burdensome state contracting guidelines and rules.

37. Of course, I am not now a certified prescriber (though I could easily satisfy the stated criteria for prescribing clinicians), because the certification requires me to provide a billing address and a shipping address where the Mifeprex can be sent to and then dispensed from—which, for the reasons I have stated, I am unable to do. And regardless of any certification requirement, I now provide and will always provide only medical care within the scope of practice for which I'm qualified. That is a well-recognized, basic standard of the medical profession.

38. As I have already noted, this approval process would be extremely challenging in the tense political climate surrounding abortion at my hospital, and it would almost certainly be subject to interference by colleagues and others who vehemently oppose abortion and therefore would object to a decision to stock

Mifeprex in our hospital system. As Chief of Staff tasked with maintaining good working relationships in my hospital, I find these risks unacceptable. They would not only interfere with my supervisory role, and the long-term positive changes for overall patient care that I am attempting to accomplish in that role, but also take valuable time away from my own practice.

39. In addition, I understand that the Mifeprex REMS would also require me to provide my patients with, and discuss and sign, a "Patient Agreement Form" describing the proper usage of, and risks associated with, Mifeprex as of March 2016. This special form requirement is unnecessary and singles out abortion in a manner that other medications, even much less safe medications, are not.

40. Informed consent counseling is a bedrock of medical care, taught as a core skill in medical school and reinforced by the American Medical Association's Code of Medical Ethics. I do not need any special requirement or form to ensure that I provide every patient with informed consent counseling, including discussion of proper usage and risks and what to do in the event that they need follow-up or emergency care. In fact, much less safe medications that I use in my chemical dependency practice, such as Sublocade®, which are controlled substances and are very high risk for patients, do not require any such "patient agreement form." Nor do the many other medications that I prescribe, that patients fill at a pharmacy, and that they take at home.

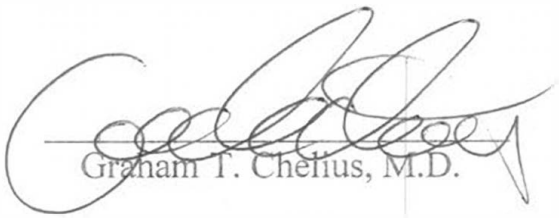
41. The bottom line is that, because of the REMS, I have been unable to provide my patients with essential health care that they need and that I am fully capable of providing. The REMS delays care, and forces patients to jump through hoops that are unnecessary, stigmatizing, and confusing. For some patients, the Mifeprex REMS makes abortion beyond reach. I greatly hope that Plaintiffs' motion for summary judgment once and for all lifts the unjustified REMS requirements from this safe, important drug, so that many other clinicians and I can provide it via prescription to our patients who need it.

42. I learned on April 13, 2021, that FDA has suspended the in-person dispensing requirement and authorized use of a mail-order pharmacy for providing patients with Mifeprex during the COVID-19 Public Health Emergency. I am exploring whether it will be possible for me to prescribe through a mail-order pharmacy under the special "supervision" requirement still imposed by FDA, and what kinds of contracts and/or billing practices may be necessary under FDA's non-enforcement guidance (which, of course, continues to treat Mifeprex differently than virtually all other drugs). I understand further that, even if I am able to take advantage of this in the short-term, this temporary allowance expires when the public health emergency ends. In short, there is an urgent need for

permanent relief through this litigation.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 4/14/, 2021



Graham T. Chelius, M.D.

EXHIBIT 2

Declaration of Julie Amaon, M.D.

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN**
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*
***admission for pro hac vice pending*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE**
RUTH HARLOW**
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN**
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]

DECLARATION OF JULIE AMAON, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Julie Amaon, M.D., declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am a board-certified family physician, licensed to practice in Minnesota, Texas, and Montana. I am trained to provide the full scope of family medicine with a focus on reproductive health care, including abortion.

3. Since July 1, 2020, I have been the Medical Director of Just The Pill, an organization founded in April of 2020 to improve access to sexual and reproductive health care for patients in rural Minnesota. To my knowledge, Just the Pill is the only mobile health center offering abortion care in the United States.

4. As a part of my practice, I prescribe mifepristone (brand name Mifeprex®) to patients seeking medication abortion. Because of restrictions imposed under the Food and Drug Administration ("FDA") Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone, I cannot simply write a prescription for mifepristone for my patients to fill at a local or mail-order pharmacy, as they would for any other medication.

5. I can and do provide all counseling and assessment for eligible medication abortion patients in a telehealth visit, which FDA permits. FDA also permits my patients to take the medication at a location of their choice. But under the REMS, my patients have to travel in person to pick up their medication—a trip

that, for patients in rural Minnesota, can mean hours of travel each way and time away from family, and jobs. The challenge of arranging for lengthy travel and time away is often hugely burdensome for my patients, and, for some, means a delay of care beyond the point at which medication abortion is available to them or denial of access to abortion care altogether. In addition to these burdens, during the COVID-19 pandemic, the mifepristone REMS has subjected my patients and their families to needless risk of exposure to a deadly virus as they travel to pick up their medication.

6. I submit this declaration in support of the Plaintiffs' Motion for Summary Judgement in my individual capacity and not on behalf of Just The Pill or any other institution.

Limited Access to Abortion in Rural Minnesota

7. Minnesota's bricks-and-mortar abortion clinics are all located in three urban population centers: the Twin Cities, Duluth, and Rochester. According to the Guttmacher Institute in 2017, 61% of Minnesota women lived in a county lacking an abortion clinic.[1] Indeed, nearly half of the rural counties in Minnesota have no sexual or reproductive health clinics at all.[2]

[1] Jones RK, Witwer E & Jerman J, Guttmacher Inst. Abortion Incidence and Service Availability in the United States, 2017, at 17 (2019), https://www.guttmacher.org/report/abortion-incidence-service-availability-us-2017.

[2] Univ. of Minn. Healthy Youth Dev. Prevention Rsch. Ctr., 2019 Minnesota Adolescent Sexual

8. As a result, patients who reside in rural areas often must drive 3 or 4 hours *each* way to access abortion care, and sometimes longer in inclement weather during Minnesota's long winters. This travel requires patients to pay and arrange for transportation, time away from work, and child care, all of which can be costly and difficult. The expenses necessitated by this travel creates particularly weighty burdens for patients living with low incomes, which is the case for 75% of abortion patients.[3] As described below, for some patients the challenges they face in raising funds and arranging for travel and time away results in significant delays in their ability to access care and can prevent them from obtaining the abortion they seek.

COVID-19 and the Expansion of Telehealth Services

9. Just The Pill was established in the Spring of 2020, as the SARS-CoV-2 virus that causes COVID-19 spread through the United States, and access to abortion care in Minnesota became increasingly limited because of pandemic-related clinic closures and drastically reduced in-person care. At that time, the provision of health care in the United States was changing dramatically. Federal and state governments urged health care providers to use telemedicine to provide

Health Report 3 (2019), https://kstp.com/kstpImages/repository/cs/files/2019_ashr_final.pdf.

[3] Guttmacher Inst., Induced Abortion in the United States (2019), https://www.guttmacher.org/fact-sheet/induced-abortion-united-states#.

care whenever possible to maximize patient access to health care while minimizing the risk of viral transmission associated with travel to health care facilities during the pandemic.

10. At that time, I was working in a family medicine clinic, and like other physicians throughout the country, my practice transformed from an almost entirely in-person practice to one in which a broad range of primary care was offered by telehealth. However, because of the REMS, medication abortion patients were still required to travel in person to a health care facility to pick up their mifepristone. For patients in rural Minnesota, this meant continuing to travel long distances to access care. Just The Pill was created with the goal of helping such patients reduce the burdens and risks of travel by offering care from a mobile health clinic that could bring services closer to the patients.

11. In the summer of 2020, as Just The Pill was raising the funds to pay for its mobile health clinic, a federal district court in Maryland entered an injunction suspending the mifepristone REMS in-person requirements for the duration of the COVID-19 Public Health Emergency ("PHE").[4] This meant that mifepristone prescribers could mail or deliver mifepristone to patients or arrange to have the medication sent from a mail-order pharmacy.[5] As a result, Just The Pill

[4] *Am. Coll. of Obstetricians & Gynecologists v. FDA* [hereinafter "*ACOG v. FDA*"], 472 F.Supp.3d 183 (D. Md. 2020).

[5] *Id.*; *ACOG v. FDA*, Civ. No. TDA-20-1320, 2020 WL 8167535 (D. Md. Aug. 19, 2020).

pivoted from its plan to treat patients from a mobile health clinic and, in October of 2020, began offering medication abortion care via telehealth to eligible patients throughout Minnesota and delivering their medication directly to them through a mail-order pharmacy. However, in January of this year, the U.S. Supreme Court issued a stay of the injunction, reinstating the mifepristone REMS in-person requirements.[6]

12. From October of 2020 until the Supreme Court reinstated the mifepristone REMS in-person requirements, Just The Pill provided medication abortion by telemedicine with delivery from a mail-order pharmacy to nearly 100 patients in Minnesota. During this period, patients would schedule a telehealth appointment with me, where we would discuss the patient's medical history and symptoms to permit me to assess whether they were eligible for a fully remote medication abortion. If their medical history and symptoms were consistent with a fully remote medication abortion, I would provide comprehensive counseling, just as I would at an in-person visit. This included discussing the medication abortion process and the risks, benefits and alternatives to a medication abortion; reviewing FDA's Patient Agreement for mifepristone; informing the patient about our 24-hour-a-day phone line in the event that they had any questions after the appointment; reading the Minnesota state-mandated information about abortion;

[6] *ACOG v. FDA*, 141 S. Ct. 578 (2021).

and answering any questions they might have, ensuring that they had all the information they needed to make an informed decision about their care. After answering any additional questions, I would ask if they consented to a medication abortion, and if so, document that consent in their medical record. I would then *again* review the instructions for how and when to take their medication, what the follow-up process was, and what they should do if they experienced any of the (very rare) complications associated with mifepristone.

13. Following the telehealth visit, I would direct the mail-order pharmacy with which I have a contract for shipping and dispensing mifepristone to send the patient a package containing the medications (mifepristone, misoprostol, and, if requested, anti-nausea medication and ibuprofen for their comfort), written instructions, the mifepristone medication guide, and our 24-hour telephone number. We tracked shipments and confirmed delivery to patients from the mail-order pharmacy; the process was efficient and effective. As with the medication abortion itself, the medical follow-up for the vast majority of patients was also completed remotely, using telephone or audio-video communications and an at-home pregnancy test. None of the nearly 100 patients we treated through this process experienced a serious complication.

14. Being able to obtain their abortion medications from a mail-order pharmacy, without an unnecessary in-person trip to a health clinic, was a huge

relief for my patients. It enabled them to end their pregnancies earlier and more safely, without the need to travel long distances, arrange for child care, and take time away and lose pay from much needed jobs—and without the risk of viral exposure that jeopardized their health and lives and that of their families for no medical purpose. In a survey during part of this time in which 45 patients participated, 16 told us that, without the ability to have a telehealth visit and have their medication delivered directly to them, they would have had to delay care for "significantly more than 2 weeks," and 2 already knew they would not have been able to access abortion care at all and would have been forced to carry their unwanted pregnancies to term.

Burdens and Risk for Patients Following Supreme Court Stay

15. After the Supreme Court reinstated the mifepristone REMS in-person requirements, Just The Pill began providing care from a mobile health clinic at locations throughout the State to help patients access care. We did all evaluation and counseling with our patients via telemedicine, but we could no longer have their medication shipped to them; instead, they had to travel to where our mobile clinic was located on a given day.

16. We attempted to drive our mobile health clinic to locations that would be most helpful for our patients. These are largely places with communities facing the greatest barriers to traveling for care—such as communities with high

concentrations of migrant farm workers; areas with high poverty rates; and communities hardest hit by the COVID-19 pandemic, including those with large concentrations of Black, Indigenous, and people of color, and one particular community with a widespread outbreak of COVID-19 among workers at a meat-processing plant. However, we are a small operation, able to travel only a few days a week to a few different places in a very large state. Even with our atypical (and highly labor intensive) care delivery model, our patients continued to suffer significant burdens and risks as a result of the travel necessitated by the REMS.

17. For example, I recently treated a patient who lived in far northern Minnesota—on the Canadian border. Based on her medical history and symptoms, she was eligible for a fully remote medication abortion. I had conducted a telehealth visit with her, but, because of the REMS, she had to travel in person to pick up her medication. She scheduled her appointment on a day when we would be driving the mobile health clinic to our farthest north destination—approximately 4 hours northwest of Minneapolis. Even so, this meant that the patient had to travel 2 hours each way to us. She did not have a car and the only way for her to get to us was by cab, which cost approximately $300. When she arrived, she quickly got out of the cab, ran to the mobile clinic, and then immediately turned around to go home with her medication. Fortunately, we were able to raise private funds for this patient to get the care she needed. She told me that had assistance not been

available to pay for her to take a cab to our mobile clinic (or had Just The Pill's mobile clinic not been available), there is no way she could have afforded to get to clinic and she would have had to carry her pregnancy to term. But for the REMS, this patient could have received her medication without ever leaving her home.

18. We recently treated a patient who had 3 children, no car, and would have had to travel 3 hours round-trip to get to the nearest bricks-and-mortar clinic offering abortion care. We were able to treat her by telemedicine, but she had no one to care for her children and was unable to arrange for transportation to pick up her medication even from our mobile health center. In order to help this patient, we drove the mobile health clinic and parked it a block from her home so that she could walk to our mobile clinic. This was an extremely unusual situation; we simply could not do that for every patient. However, if we had not done so for this patient, she would not have been able to have the abortion she sought. But for the REMS in-person requirement, we could have had the medication sent directly to her following her telehealth visit.

19. Another patient with 4 or 5 children at home was trying to arrange to travel to our mobile health clinic to pick up her medication. This patient lived a 5-hour round-trip car ride from the nearest bricks-and-mortar clinic offering abortion care. She had a car, but it was not reliable, even for the 1-hour drive to our mobile clinic. We offered financial assistance for a cab, but this patient could not take

advantage of it, because she could not fit all of her children in the cab. Her spouse was a long-distance truck driver who was on the road most of the time, and, since the patient was new to the area, she did not have anyone she could turn to for child care assistance. To help this patient, we were able to drive the mobile health clinic to her town; however, this meant a delay of more than a week before she could obtain care. But for the REMS, we could have had her medication delivered directly to her home without such delay.

20. I have had numerous patients who have had to cancel appointments at the last minute because they can't get time off work, find child care, or forgo other obligations with which this travel interferes, or because their travel arrangements have fallen through. For some of these patients, when they tried to reschedule, we had to tell them that they were no longer eligible for a medication abortion because they were beyond 10 weeks in pregnancy. When that happens, we refer them to other abortion providers who offer in-clinic procedures, but, since there are so few abortion clinics in the state, this generally means even lengthier and more costly travel, and therefore more delay. Given the challenges that prevent such patients from accessing even our mobile clinic, I feel certain that some were never able to make the journey to a brick-and-mortar clinic in one of Minnesota's urban centers and therefore were forced to continue their pregnancies and have a child. But for

the REMS, these patients could obtain care without delay by telemedicine and home delivery of medication.

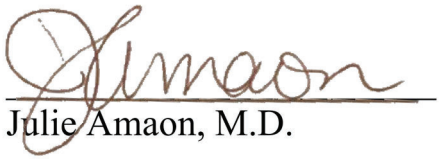
Barriers to Prescribing Mifepristone

21. Even though medication abortion could be safely provided in primary care and other health care settings throughout the state, the REMS requires health care providers to register as certified prescribers with the REMS program and stock mifepristone onsite for in-person dispensing. I have seen how these requirements prevent would-be mifepristone prescribers from providing this essential care to their patients. I know clinicians who would have prescribed mifepristone but were prevented from stocking and dispensing it onsite by others at the facilities in which they practice. For example, the family medicine clinic where I did my residency training was not permitted to stock mifepristone onsite because of opposition from someone at the institution. If it were not for the REMS, however, clinicians would have been able to send in mifepristone prescriptions to a pharmacy, as they do for virtually all other medications. Instead, because of the REMS, clinicians who practiced at the clinic could not provide mifepristone to their patients. The mifepristone REMS creates unnecessary barriers to the provision of care.

22. Earlier this week, FDA announced that it would suspend enforcement of the REMS in-person requirements during the COVID-19 PHE. This is

extremely good news for my patients, who now again have the opportunity to receive care by telehealth and have their medication delivered directly to them from a mail-order pharmacy. However, this non-enforcement policy is limited to the PHE: when the PHE ends, the REMS in-person requirements will again harm my patients as they have in the past.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on April 14, 2021.



Julie Amaon, M.D.

EXHIBIT 3

Declaration of Joey Banks, M.D.

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN**
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*
***admission for pro hac vice pending*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE**
RUTH HARLOW**
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN**
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]

DECLARATION OF JOEY BANKS, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Joey Banks, M.D. declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am a family medicine physician. I work at Blue Mountain Clinic in Missoula, Montana, where I have been providing care since 2011. I currently provide and train residents in reproductive health care, including abortion, at the Blue Mountain Clinic and also provide such care at a clinic in Tulsa, Oklahoma.

3. In addition, I serve as the Chief Medical Officer for Planned Parenthood of Montana, a position I have held since 2019. In this capacity, I supervise the medical staff at all Planned Parenthood sites statewide and also provide reproductive health care to patients.

4. In my practice I prescribe mifepristone (brand name Mifeprex®) to my patients both for pregnancy termination and in cases of pregnancy loss (where mifepristone assists in safely and efficiently completing the miscarriage). I have provided abortion and miscarriage care to patients for 20 years and, over the years, have provided such care to many people who lived in areas where care is difficult to obtain—including in Alaska, Maine, Montana, and, most recently, in Oklahoma.

5. I am a member of the National Abortion Federation, the American Academy of Family Physicians, and the Montana Academy of Family Physicians. I am also a member of the Society of Family Planning ("SFP"). I understand that SFP is a plaintiff in litigation challenging FDA's imposition of a Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone, and write this declaration in support of SFP's Motion for Summary Judgment. I do so in my individual capacity and as an SFP member, and do not speak on behalf of Blue Mountain Clinic, Planned Parenthood, or any other institution.

6. Until a couple of years ago, Blue Mountain Clinic was the only clinic in Missoula where patients could access abortion care. The Blue Mountain Clinic is located near a perinatologist's office. A perinatologist is an obstetrician who specializes in maternal-fetal medicine and has special training in high-risk pregnancy care. Perinatologists sometimes use mifepristone to induce labor in late pregnancy.

7. The perinatologist near my clinic did not stock mifepristone, but occasionally wanted to administer it to his patients to induce labor in late pregnancy. Knowing that I stocked and provided mifepristone to my patients, in 2018 the perinatologist approached me about whether I would be amenable to his sending his patients to see me just to obtain the mifepristone, and then he would re-assume care after the patient left my clinic.

8. When I asked the perinatologist why he didn't stock mifepristone himself, he said it was because he was worried that by stocking mifepristone he would unwittingly be placed on a list of abortion providers. The perinatologist was aware of the history of violence and harassment by anti-abortion activists and was concerned that if the list of mifepristone prescribers required by the REMS were somehow made public, it would put him in danger.

9. The perinatologist was affiliated with and provides services at a local hospital in Missoula, Montana. When I asked why he didn't just ask the hospital to stock mifepristone in its formulary, he said that he did not want anyone in the hospital to presume he was pro-choice.

10. This is not the only instance in which I have encountered clinicians who are unwilling to stock mifepristone even though it would benefit their patients. For instance, since 2013, I have been providing reproductive health care training to family medicine residents at Blue Mountain Clinic. My training includes, among other things, medication abortion, procedural (sometimes called "surgical") abortion, and miscarriage management. For many

years, I have taught residents to treat patients seeking medication abortion with a regimen of 200mg of mifepristone followed by 800mg of misoprostol; and, since 2018, based on new, high-quality medical research, I also began teaching them this two-drug regimen for the medical management of miscarriages. Although both can be accomplished with misoprostol alone, evidence supports the two-drug regimen as the superior regimen.

11. On numerous occasions, I have been contacted by physicians I previously trained, telling me that the health care facility where they work does not stock mifepristone, and that they felt uncomfortable asking leadership at their health care facility to begin stocking mifepristone, or that they knew their clinic simply would not stock mifepristone. They all wanted to know whether they could still care for patients who sought a medication abortion or suffered a miscarriage, even without mifepristone. In light of these conversations, I now explain to the residents I train that if their health care facility does not stock mifepristone, they can consider prescribing misoprostol alone for either early abortion or miscarriage treatment, but that it is less effective and that the two-drug regimen, including mifepristone, is the superior regimen

12. In my experience, the mifepristone REMS is interfering with practitioners' provision of evidence-based medicine. Some clinicians fear professional repercussions if they try to persuade their colleagues to stock and dispense mifepristone onsite. And some are so concerned about the stigma and threat of violence surrounding the provision of abortion that they are unwilling to register their names and addresses with the mifepristone distributer, as required by the REMS. The prospect of this "abortion provider list" being leaked to the public is enough to prevent clinicians from providing what they deem the best medicine for their patients.

13. In sum, the mifepristone REMS prevents clinicians from providing solid evidence-based medicine due to the stigma and fear associated with having to register with the

drug manufacturer and stock the medication onsite.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on April 12, 2021.

Joey Banks, M.D.

EXHIBIT 4

Declaration of Jared Garrison-Jakel, M.D.

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN**
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*
***admission for pro hac vice pending*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE**
RUTH HARLOW**
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN**
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]

DECLARATION OF JARED GARRISON-JAKEL, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Jared Garrison-Jakel, M.D., declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am a board-certified family medicine and addiction medicine doctor in Guerneville, California, and a member of the California Academy of Family Physicians ("CAFP"). I understand that CAFP is a plaintiff in this litigation challenging the U.S. Food and Drug Administration's imposition of a Risk Evaluation and Mitigation Strategy ("REMS") for Mifeprex, and write in support of that litigation. The Mifeprex REMS causes injury to me and my patients. But for the REMS, I could and would provide Mifeprex to my patients.

3. I received my undergraduate degree from Pomona College in 2005, a Master's in Public Health from the University of California Berkeley in 2009, and my medical degree from the University of California Irvine School of Medicine in 2010. I subsequently completed an internship and residency in family medicine at Sutter Medical Center of Santa Rosa in California.

4. I am trained in both medication and surgical abortion and provided those services while in my residency at Sutter Medical Center of Santa Rosa.

5. Since 2013, I have practiced at Russian River Health Center in Guerneville, California ("Russian River"). I submit this declaration in my individual capacity and— besides CAFP—not on behalf of any institution with

which I am associated, including the health center.

6. Russian River is a federally qualified health center ("FQHC"). FQHCs offer primary health care services to low-income populations in medically underserved areas. Guerneville, where Russian River is located, is an economically depressed city with virtually no other health care facilities. Our health center is located about 30 minutes away from any other doctor's office.

7. Many of my patients have little access to transportation outside of the community where Russian River is located. This lack of transportation makes it difficult to access even urgent health care services. For example, I treated one patient who had a terrible cut in her hand—the laceration reached the tendon. I told this patient that she needed to see a hand surgeon due to the severity of the laceration, but the patient explained that such travel would be impossible for her. She told me, "Doc, either you fix it now or no one's fixing it."

8. As explained below, because of the REMS, medication abortion is not available in the health center where I work. As a result, I have had to turn away patients who need abortion care. The closest clinic that offers abortion services is a one-hour round-trip from our health center. Traveling such a distance is a significant impediment for the populations I serve, who generally struggle to afford and arrange for things like transportation and child care. And, making this journey may very well also require my patients to miss work, and therefore lose wages—

that is, if they can get time off work at all; at the low-wage jobs where my patients typically work, there is often no paid leave. The reality is that it can be difficult or impossible for my patients to overcome all of these barriers.

9. I am medically qualified to provide Mifeprex to my patients who request a medication abortion. The only reason why I am not able to do so is because of the requirement that I stock and dispense Mifeprex on site.

10. I am aware that at least one of my colleagues, who holds a position of authority at our institution, is opposed to abortion and would not consent to Mifeprex being stocked and dispensed in our health center. (For the same reason, we cannot provide surgical abortion services here.) However, I am also aware that this colleague would not interfere with my writing a prescription for Mifeprex in the privacy of my office for a patient to fill at a pharmacy—and there are two pharmacies very close to the health center where I work; one is only a block away. But for the REMS, I could and would provide medication abortion care to my patients (and would do so in compliance with all federal segregation guidelines for FQHCs that provide abortion services).

11. Because of the REMS, I have been unable to treat my patients in accordance with my medical judgment. Multiple patients have come to me with unwanted pregnancies at less than ten weeks, who requested—and were eligible for—medication abortions. However, because of the REMS, I had to deny them

this care—delaying their abortion, to the extent that they could obtain the abortion at all. Indeed, I am always reluctant to refer a patient to another health care facility, whether for abortion or any other medical service; given the financial challenges that my patients almost uniformly face, which are often compounded by other barriers and stressors (such as mental health disorders, substance use disorders, or homelessness), such a referral usually means that they will be significantly delayed in accessing medical care, or not obtain it at all.

12. There are three central concerns with delaying abortion care. First, if a patient is delayed past ten weeks of pregnancy, she typically will no longer be able to obtain a medication abortion and will instead need to have an in-office clinical procedure, which may be an inferior option given her circumstances. Second, while abortion is extremely safe, and far safer than remaining pregnant and carrying to term, the risk of complications increases as the pregnancy progresses. I can recall at least one patient who came to me at a point in pregnancy when she was still eligible for a medication abortion but, because I could not write her a prescription for Mifeprex, ended up having a more invasive and time-consuming second-trimester dilation and evacuation abortion procedure over a month later. Third, delaying a patient's abortion means that the patient stays pregnant longer, and thus must incur the serious risks and discomforts associated with pregnancy for longer.

13. Moreover, because of the REMS, at least one of my patients was prevented from having a desired abortion at all. This patient had a history of sexual trauma and struggled with substance use disorders. She was extremely distressed to learn that she was pregnant, and presented to me seeking a medication abortion. To add to the complications of her situation, she did not feel that she could disclose her desire for an abortion to her partner. I initially referred her to the nearest clinic providing first-trimester abortion services, but she was unable to make the journey to that clinic for her appointment. I saw her again in her second trimester, when she reiterated that she did not want to carry the pregnancy to term. At that point, I referred her to the nearest provider of second-trimester abortions, which is approximately three hours round-trip from Guerneville. I know that the care team at that facility worked diligently to support her in accessing abortion care, including trying to arrange transportation for her. Nevertheless, because of the many challenges in her life, she missed multiple appointments there as well. This patient ultimately ended up carrying the pregnancy to term. I have grave concerns about how this unintended pregnancy has affected her life; when I'd seen her, she communicated that the pregnancy had worsened her suffering around her sexual trauma history and medication dependency. Moreover, this patient did not obtain adequate prenatal care during her first or second trimesters because this was not a pregnancy she had intended to carry to term. Needless to say, denying this patient

the care she so desperately wanted and needed was not in accordance with my best medical judgment.

14. In short, the Mifeprex REMS has prevented me from fulfilling my personal, professional, and ethical obligations to provide my patients with the medical care they need, which I am qualified to and would otherwise provide.

15. I am aware that the FDA just announced that, for the remainder of the COVID-19 Public Health Emergency, it is suspending enforcement of the requirement that patients obtain Mifeprex in person at a health center and instead allowing patients to obtain their medication by mail or from a mail-order pharmacy acting under the supervision of a certified REMS prescriber. Although this is an important step in the right direction, even under this short-term policy, the FDA continues to treat Mifeprex differently than any other drug I prescribe. I am working to understand what this "supervision" requirement entails (such as with regard to billing) and determine whether or not I will be able to take advantage of this temporary policy shift. Regardless, a permanent fix is essential to ensure that my patients can access medication abortion care without facing needless, and sometimes insurmountable, hurdles.

I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed on April 14th, 2021, in Guerneville, California.

Jared Garrison-Jakel, M.D.

EXHIBIT 5

Declaration of Erin King, M.D.

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN**
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*
***admission for pro hac vice pending*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE**
RUTH HARLOW**
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN**
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]

DECLARATION OF ERIN KING, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Erin King, M.D. declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am a board-certified Obstetrician Gynecologist ("Ob-Gyn") licensed to practice in Illinois and Missouri. I treat patients principally at a general Ob-Gyn practice in St. Louis, Missouri, and at the Hope Clinic for Women ("Hope Clinic") in Granite City, Illinois, where I also serve as the Executive Director. I provide patients with the full scope of obstetric and gynecological care, including abortion care.

3. I am a member of the American College of Obstetricians and Gynecologists, the National Abortion Federation, and the Society of Family Planning ("SFP"). I understand that SFP is a plaintiff in this litigation challenging the Risk Evaluation and Mitigation Strategy ("REMS") that the Food and Drug Administration ("FDA") imposes for mifepristone (brand name Mifeprex®). I write this declaration in support of Plaintiffs' Motion for Summary Judgment, on my own behalf, and not on behalf of Hope Clinic or any other institution.

4. I am a certified prescriber under FDA's mifepristone REMS. I prescribe mifepristone as part of a medication abortion regimen and for patients seeking medical management of miscarriage. I also provide training in medication abortion and other abortion and reproductive health care.

5. I am aware of clinicians who would prescribe mifepristone for medication abortion and miscarriage care for their patients if they could send in a prescription to a local or mail-order pharmacy as they do with nearly all other medication. However, the mifepristone REMS—which requires clinicians to register as certified prescribers and to stock and dispense mifepristone in their offices—has prevented them from using mifepristone in their patient care. Physicians I have trained have often told me that they are unable to find employment with practices that are willing to stock mifepristone and, as a result, were not able to provide medication abortion or miscarriage care using mifepristone to their patients, though they would have been able to provide this care if they could simply write a prescription.

6. The mifepristone REMS also imposes significant burdens on my patients. Because of the REMS, my patients whom I can evaluate and counsel via telemedicine have had to travel unnecessarily to my clinic for their medication. They have had to find and pay for transportation and child care and take time away from jobs that pay by the hour or day. This is particularly burdensome for my many patients who live with low incomes and have to travel long distances, from rural parts of southern Illinois, to get to my clinic. In addition, during the COVID-19 pandemic, the REMS has put them and their families at needless risk for contracting a deadly virus as they travel in person to pick up medication that they

could otherwise safely receive by mail at home.

7. Last year, a federal district court in Maryland issued an injunction suspending the mifepristone REMS in-person requirements for medication abortion for the duration of the COVID-19 federal Public Health Emergency ("PHE").[1] The injunction permitted me to contract with a mail-order pharmacy to ship mifepristone to my eligible patients. That meant that, for my medication abortion patients who did not require in-person assessment, I could provide all counseling and assessment in a telehealth visit and then have the medication delivered directly to them from the mail-order pharmacy.

8. On the day we began offering patients the option to receive their prescription through the mail-order pharmacy, I treated a patient who had had an appointment to come to the clinic for a medication abortion but had had to cancel because she could not get time away from work and could not find anyone to stay with her children. She told me that she would have had to forgo an abortion altogether if we had not been able to offer her a telemedicine visit and delivery of her medication, because she did not think she would ever be able to make the arrangements necessary to get to the clinic in person. But, because the REMS in-person requirements were enjoined, she was able to have a safe abortion from the

[1] *Am. Coll. of Obstetricians & Gynecologists v. FDA* [hereinafter "*ACOG v. FDA*"], 472 F.Supp.3d 183 (D.Md. 2020); *ACOG v. FDA*, Civ. No. TDA-20-1320, 2020 WL 8167535 (D.Md., Aug. 19, 2020).

safety and privacy of her own home.

9. Unfortunately, however, the U.S. Supreme Court entered a stay of the injunction, reinstating the in-person requirements.[2] As a result, for the past three months I have again been forced to require patients seeking medication abortion care to travel to the clinic to pick up their medication.

10. This requirement imposes substantial burdens on my patients. Since the Supreme Court reinstated the REMS in-person requirements, I have seen numerous patients who needed no in-person assessment but nevertheless had to travel multiple hours, each way, to come to my clinic to pick up their medication. These patients have had to bear the costs and burdens of arranging travel, time away from work, and child care, when they could just as safely have obtained their prescription by mail and avoided all of these burdens.

11. Needing to make these arrangements and raise funds for this travel has often delayed my patients' care—sometimes beyond the point when they can have a medication abortion. I recently saw a patient who wanted a medication abortion but was 13 weeks pregnant and therefore had to have an in-clinic procedure. She was very upset, explaining that she had rescheduled her appointment numerous times because she could not arrange for travel or find someone to take care of her children—and during the pandemic, she could not

[2] *ACOG v. FDA*, 141 S. Ct. 578 (2021).

bring her children with her to our clinic, because we do not allow anyone other than the patient to enter in order to mitigate viral spread. But for the mifepristone REMS, I could have treated this patient in a telemedicine visit and had her medication delivered to her at home while she was still eligible for a medication abortion. This patient is not alone; I see patients every week with one variation or another of this story.

12. I am able to provide care entirely by telehealth for a wide array of other medical needs. For instance, I regularly use telehealth to diagnose, treat, and counsel patients regarding urinary tract infections, vaginitis, rashes, and contraception needs. In my practice, we also conduct prenatal and post-partum visits remotely. We can even examine a patient's sutures and evaluate how well the patient is healing after surgery in a telehealth visit. I can just as safely and effectively evaluate and comprehensively counsel eligible medication abortion patients in a telehealth visit. However, because of the REMS, my patients who require mifepristone have had to suffer needless burdens and risks that my patients who can obtain care entirely by telehealth are able to avoid.

13. Earlier this week, FDA announced that it would suspend enforcement of the REMS in-person requirements during the COVID-19 PHE. I am very pleased that my patients receiving care by telehealth can now have their medication delivered directly to them from a mail-order pharmacy without the

costs, risks, and burdens of a needless in-person trip. However, when the PHE ends and this non-enforcement policy expires, the REMS in-person requirements will again impose substantial burdens on my patients.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on April 14, 2021.

Erin King, M.D.

EXHIBIT 6

Declaration of
Charisse M. Loder, M.D., M.SC.

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN**
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*
***admission for pro hac vice pending*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE**
RUTH HARLOW**
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN**
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]
DECLARATION OF CHARISSE M. LODER, M.D., M.SC., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Charisse M. Loder, M.D., M.Sc., declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am an obstetrician-gynecologist trained in abortion care and a member of the Society of Family Planning ("SFP"). I am a Clinical Assistant Professor of Obstetrics and Gynecology at the University of Michigan Medical School. My practice is located at the Women's Clinic at Von Voigtlander Women's Hospital in Ann Arbor, Michigan. I have also practiced as an obstetrician-gynecologist at Planned Parenthood in Ann Arbor.

3. I received my undergraduate degree from Cornell University in 2003, and my medical degree from Pennsylvania State University in 2011. I did my residency in Obstetrics and Gynecology at the University of Rochester, where I served as Chief Resident, and then completed a fellowship in Family Planning and received a Master of Science degree in Health and Health Care Research at the University of Michigan.

4. In my current practice, I provide a range of obstetrics and gynecology care, and specialize in miscarriage management, complex contraception and sterilization, and abortion care.

5. I submit this declaration in support of Plaintiffs' Motion for Summary Judgment. I do so only in my individual capacity and as a member of SFP, not on behalf of any institution with which I am affiliated.

6. Mifeprex is an important drug for the provision of abortion and miscarriage care. I advocated to make this medication available within the Women's Clinic in order to offer our patients the best possible care at our own institution, without having to refer them elsewhere.

7. While I am currently able to prescribe mifepristone to my patients, attempting to bring the Women's Clinic at the University of Michigan into compliance with the mifepristone (brand name Mifeprex®) Risk Evaluation and Mitigation Strategy ("REMS") was an extremely complicated process that took five years (and a substantial investment of time, resources, and professional capital by me and other colleagues). During these five years, my colleagues and I were forced to refer patients who needed medication abortion care to other institutions. When patients are referred elsewhere for abortion care, many experience delays or are even prevented from accessing this time-sensitive care. We were also unable to offer Mifeprex for miscarriage and second-trimester abortion care, even though Mifeprex enhances the efficacy of those treatments. There is absolutely no medical reason for FDA to impose these barriers to patients obtaining this safe and effective medication.

8. My involvement in the process of trying to make Mifeprex available at the University of Michigan began when I arrived at the University six years ago, in 2015. But conversations surrounding Mifeprex at the University of Michigan began seven years ago, in 2014. As of 2014, the only patients who could access mifepristone through the University of Michigan were those seeking treatment for Cushing's syndrome: University clinicians were able to prescribe mifepristone under the brand name Korlym, and the patients filled those prescriptions through a mail-order pharmacy. However, patients in need of mifepristone under the brand name Mifeprex, for reproductive health care, could not access the medication through any University provider.

9. As a first step, I had to get approval to add Mifeprex to the University's drug formulary from the University's Pharmacy and Therapeutics Committee ("the Committee"), which is composed of pharmacists and physicians from a variety of clinical specialties. As discussed above, I was not the first physician to attempt to do so; in 2014, other physicians had participated in multiple meetings with the Committee during which they advocated for adding Mifeprex to the formulary. Ultimately, these conversations stalled because those physicians were unable to invest the immense amounts of time required to move this process forward.

10. Between 2015 and 2016, I participated in approximately four Committee meetings relating to Mifeprex. To assist in the Committee's evaluation of Mifeprex, the Committee asked me and my colleagues to provide literature on Mifeprex's safety and indications for use, which we did. These meetings were each about an hour long, and I individually spent at least 20 additional hours researching and preparing presentations about Mifeprex's safety and efficacy, as well as writing guidelines for its use.

11. Finally, in 2016, the Committee approved Mifeprex for the University formulary. None of this would have been necessary—the Committee would not have been involved at all—if we could simply issue our patients a prescription to fill at a pharmacy instead of having to stock and dispense Mifeprex onsite.

12. But getting Mifeprex on our hospital's formulary still did not mean that University of Michigan clinicians could start prescribing Mifeprex to patients. Placing a drug "on formulary" means that the drug is approved for safe use by the hospital. But, in order to make Mifeprex available "in clinic" for patients, the University of Michigan first had to order and stock this medication. And it took me *three* more years of advocacy to achieve this second step.

13. In 2018, a pharmacist in the gynecology department suggested that I form a task force to develop protocols for Mifeprex use in-clinic because the process had stalled out. I believe that my colleague suggested that I create such a

task force in order to alleviate concerns throughout the University about how to comply with the Mifeprex REMS and to accelerate the process of actually stocking and dispensing Mifeprex. I have never heard of such a task force being formed for the introduction of other drugs or devices into University practice. For example, we frequently integrate new intrauterine contraceptive devices (IUDs) into our practice, and have never had to develop protocols about how to prescribe them. But I believed that without a physician champion and a committee specifically focused on this issue, Mifeprex would never be made available in our clinic.

14. Accordingly, I organized and created a multidisciplinary task force to develop various protocols for ordering, stocking, prescribing, and dispensing Mifeprex at the Women's Clinic. This task force is made up of gynecology and family medicine physicians, nurses, clinic managers, pharmacists, and electronic medical record (EMR) specialists. The task force was charged with finalizing protocols to address how Mifeprex is ordered, administered, and stored, as well as addressing safety and reimbursement concerns surrounding the storage and dispensing of Mifeprex at our clinic. In a large health care institution like ours, where every organizational decision requires approval from multiple stakeholders, none of these decisions were simple.

15. I first convened this task force in October 2018, and the task force met every six weeks until Mifeprex was available in clinic. The task force met for

about an hour each time—and that is only the tip of the iceberg. Since October 2018, I have spent at least 80 hours of my time preparing for and/or completing follow-up work relating to task force meetings (such as preparing education materials for clinical staff), as well as participating in numerous *non*-task force meetings with stakeholders to discuss protocols to ensure compliance with the REMS as we integrate Mifeprex into clinical practice. For instance, I met with EMR representatives to propose edits to our electronic medical records in order to track Mifeprex administration in patient records. I attended separate meetings with the Women's Clinic manager, insurance verification team, and billing team related to the University's financial and reimbursement concerns around the dispensing of Mifeprex onsite. And I consulted on strategies to communicate guidelines for Mifeprex administration with staff, including developing REMS-compliant protocols for nurses who may want to "opt-out" of any involvement in the dispensing of Mifeprex. If not for the REMS, I would not have had to involve all of these other clinicians and stakeholders within the University and invest so many hours of my time and professional resources into developing system-wide protocols to integrate Mifeprex into hospital practice. I would simply have written my patients a prescription.

16. The Mifeprex REMS also requires that clinicians register with the drug's distributor in order to become a certified prescriber. As an initial matter, this

requirement is medically unnecessary: Mifeprex is a safe and straightforward medication; the clinical competencies necessary to safely prescribe it are very common; and in general, and as a legal and ethical matter, my colleagues and I do not prescribe any treatment unless it is within our competency to do so. But the prescriber certification requirement also posed numerous obstacles to the provision of Mifeprex at the University of Michigan.

17. First, task force members raised concerns that the University would face legal liability if clinicians who were not acting pursuant to a REMS prescriber agreement prescribed this drug. We spent many meetings discussing protocols to prevent violations of the REMS.

18. Second, members of the task force were concerned about how to store Mifeprex to ensure that only certified prescribers can access it. As a result, the task force spent numerous meetings discussing how to properly secure the Mifeprex stock with locks, and how to determine which clinicians have access to the locked area.

19. Third, because of the prescriber certification requirement, the University of Michigan must update its EMR system and pharmacy database each time a physician registers as a certified provider. These updates are costly and require staff time. These systems must be updated constantly to alleviate a concern that someone will prescribe Mifeprex in violation of the REMS.

20. These organizational concerns related to prescriber certification stem not from any mistrust of physicians, but from concerns about compliance with the REMS.

21. I would never have been able to provide mifepristone to my patients if it were not for the tenacious advocacy and time commitment my colleagues and I invested into this effort. As it was, for more than five years, the REMS prevented me and all of my colleagues from providing that care to our patients and necessitated that we refer patients outside of the University of Michigan system. I know that many of my colleagues have had the same experience, because over the years, I have frequently been contacted by colleagues inquiring whether they were permitted to prescribe Mifeprex to their patients, and I had to tell them that—because of the REMS—the answer was no.

22. And my situation at the University of Michigan is by no means unique. I am regularly contacted by clinicians at other academic medical centers who are seeking advice on how to navigate the REMS in order to stock and dispense Mifeprex at their institutions.

23. Clinicians outside the University of Michigan have also shared with me that they have not integrated Mifeprex into their practice because they fear that completing the REMS prescriber certification requirement would place them on a registry of abortion providers and thus make them targets of anti-abortion

harassment or violence. If clinicians could simply write a prescription for Mifeprex without this obstacle and the other obstacles the REMS imposes, I believe that many more clinicians, in a wider swath of our state, would do so.

24. While abortion care is extremely safe, the risks associated with abortion increase as pregnancy advances. Therefore, delaying a patient's abortion care increases the risks she faces.

25. This delay also pushes patients past the point at which a medication abortion, or any abortion care, is available to them at all. When I worked at Planned Parenthood, I often saw patients who had been referred there by their primary provider because their provider does not provide medication abortion care. But, because of the delay caused by this referral, by the time these patients got to Planned Parenthood, they were frequently too far along in their pregnancies to be eligible for a medication abortion—even though they preferred that option and that option would have been most clinically suitable for them. Because of this delay, these patients were only eligible for aspiration or dilation and evacuation ("D&E") abortion, in-clinic procedures that are significantly more expensive than medication abortion. And some of these patients could not afford these more expensive in-clinic procedures and ultimately were unable to get an abortion at all.

26. My patients at Planned Parenthood frequently told me about the burdens they faced traveling to us for care: paying for transportation, arranging

child care, taking time (often unpaid) off from work, and more. Some of these patients traveled great distances: there are very few abortion providers in Northern Michigan or in Michigan's Upper Peninsula, and many of our patients traveled more than one and a half hours, and up to 10 hours, to obtain abortion care. Many of these patients shared that they could not access abortion care in their local community.

27. In addition to being an important part of safe, effective early abortion care, Mifeprex has other clinical indications, such as in medical management of pregnancy loss (miscarriage) and labor induction abortions during the second trimester. In both of these clinical circumstances, pretreatment with mifepristone reduces the length of the treatment and, as a result, reduces the risk of complications.

28. At the University of Michigan, my colleagues and I care for patients undergoing second-trimester labor induction in cases of pregnancy loss, or where the patient seeks abortion because of a diagnosis of fetal anomalies or due to significant risk to maternal health or life. During this process the patient experiences all the pain and physical consequences of labor. Clinicians often prescribe Mifeprex to patients going through this process, in order to make it easier and faster. When clinicians are unable to add Mifeprex to their treatment regimen,

many patients and their families suffer both emotional and physical tolls from longer labor inductions.

29. After five years of advocacy and hundreds of hours of advocacy by a few dedicated clinicians and stakeholders, Mifeprex finally became available onsite at the University of Michigan in late September 2019. But even now, the work continues: although Mifeprex is available at the Von Voigtlander Women's Hospital (where the Women's Clinic is located), I am still expending hours of effort to work to make Mifeprex available at our six OB/GYN outpatient sites, where clinicians continue to struggle to develop systems to stock and store Mifeprex consistent with the REMS. As a result, patients in those communities must travel longer distances (up to 40 miles round-trip) to get to our hospital for care, rather than being able to obtain a prescription for Mifeprex at their local outpatient site to then fill through a retail or mail-order pharmacy.

30. The Mifeprex REMS made this process extremely burdensome, requiring both an institutional champion (myself) willing to expend more than 80 hours of work and significant professional capital, and more institutional resources than I have seen for any other medication that has ever been made available in clinic at the University of Michigan. The five-year delay in Mifeprex's availability in clinic harmed patients.

hours of work and significant professional capital, and more institutional resources than I have seen for any other medication that has ever been made available in clinic at the University of Michigan. The five-year delay in Mifeprex's availability in clinic harmed patients.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 14, 2021.

Charisse M. Loder, M.D., M.Sc.

EXHIBIT 7

Declaration of Jane Roe, M.D.

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN*
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE*
RUTH HARLOW*
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN*
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]

DECLARATION OF [redacted], M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

[redacted], M.D., a/k/a/ Jane Roe, M.D., declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am a Family Medicine doctor trained in abortion care. I live and practice in a rural area in the western United States, approximately 100 miles away from the nearest abortion clinic. I am seeking to proceed pseudonymously out of fear of being exposed—nationally and in my small, rural town—as an abortion provider. In light of the extreme harassment and violence, including murder, that has been perpetrated against abortion providers in the United States, I attempt to keep my provision of abortion care as private as possible; I am painfully aware that my primary practice does not have the safeguards in place that exist at the abortion clinics (several hours away) where I work part-time—bulletproof glass, violent intruder protocols, alarm button, separate entrance for providers, and so on. Moreover, given the significant abortion stigma in my community, I expect that I would lose many of my non-abortion patients at my primary practice if the fact of my abortion provision were widely known.

3. I am a member of Plaintiff Society of Family Planning, and I submit this declaration in support of Plaintiffs' Motion for Summary Judgment. I do so only in my individual capacity and not on behalf of any institution with which I am affiliated.

4. Attempting to comply with the Mifeprex REMS has been time-consuming, stressful, and professionally compromising. Because of the REMS, my ability to care for my patients in accordance with their needs and with my medical judgment has been conditioned on my seeking (and gaining) approval and assistance from countless individuals and committees within my health care institution. If not for the REMS, I could have simply written a prescription for Mifeprex for my patients to fill at a local or mail-order pharmacy, rather than having to mount a workplace lobbying campaign, and jeopardize my professional standing, in order to provide this safe medication onsite to my patients who need it.

5. I am a full-spectrum Family Medicine physician. In addition to my three years of residency, I completed a Family Medicine fellowship in obstetrics. I often care for three or four generations within a family—delivering a baby one day and caring for her grandmother the next. I perform a range of obstetric and gynecological services, such as cesarean sections, tubal ligations, leeps (which entails removing pre-cancerous lesions from the cervix), endometrial biopsies, and insertion and removal of intrauterine contraceptive devices.

6. I also provide miscarriage management, including by prescribing medications to evacuate the contents of a patient's uterus. When using medications to manage a miscarriage, it is the standard of care to use both Mifeprex and misoprostol, the same two drugs used in the FDA-approved medication abortion

regimen. Thus, as discussed further below, the restrictions on Mifeprex impact my ability to provide both abortion and miscarriage care.

7. I work at a hospital and affiliated clinic within a large health care system that includes multiple hospitals, each of which has one or more affiliated clinics. Many of my patients are low-income; virtually all are rural; and many travel to us from medically underserved areas in our state. Indeed, some of my patients live in areas where there are no roads—only snowmobile access in the winters.

8. Over the years, my colleagues and I have had multiple patients ask if we could provide a medication abortion, but—because we could not write them a prescription for Mifeprex to fill at a pharmacy—we had to refer all of these patients elsewhere for care. The nearest abortion clinic is a 200-mile round-trip, and some of these patients never made the journey, instead returning later for prenatal care. I recall one adolescent patient who told my colleague that she had repeatedly scheduled appointments at the abortion clinic, only to have to cancel multiple times because she simply could not make it there.

9. So, in February 2017, along with a few colleagues, I began the process of trying to get Mifeprex added to our hospital's formulary. The formulary is the list of medications approved for use by the pharmacy committees for our hospital and for our health care system, and then made available at our hospital for

dispensing or administering to patients. Based on conversations I had with colleagues about attitudes towards abortion at our institution, I concluded that there was a greater likelihood of my gaining approval to add Mifeprex to our formulary and dispense it in my office, rather than gaining approval to perform surgical abortion services in our operating room. That is because the latter would require the involvement of many clinicians, including nursing staff, certified scrub technicians, and anesthesia providers, and would thus require (at a minimum) approval from the CEO of the hospital and the departments overseeing each of those categories of clinicians, as well as the development of opt-out procedures for the supporting clinical staff.

10. Attempting to add Mifeprex to our formulary was a major undertaking. First, we had to obtain approval from the pharmacy committee at our hospital. Once that committee agreed to move forward with the process, we could elevate the request to the pharmacy committee for the entire health care system.

11. Over the next six months, we were delayed time and again in trying to get a decision from that system-level pharmacy committee—including being advised by a representative of the committee to delay raising the issue of Mifeprex until our request could undergo further "informal vetting," and then being bumped from the agenda for the committee's once-a-month meeting at least three times. In addition, the pharmacy committee representative insisted that *we* complete the

"new drug review" analysis for Mifeprex—a time-consuming assignment that, to my knowledge, is always completed by the system-level pharmacy committee, not by the hospital-level pharmacy committee or the individual physicians or pharmacists making the request. I believe this was demanded of us only because of the controversy and stigma surrounding abortion in our community, as in many places in this country.

12. Throughout the six months that we were slogging through this process—which would not have been necessary if not for the REMS—I was forced to turn away patients who needed my care. I know with certainty that, as a result, at least one of my patients was delayed past the point in pregnancy when she could obtain a medication abortion at all—which is available only up to 10 weeks of pregnancy—and had to travel 200 miles round-trip to have a surgical abortion instead. While abortion is one of the safest procedures in modern American medicine, and far safer for a woman than remaining pregnant and carrying to term, the risks associated with abortion increase as pregnancy advances. Thus, delaying a woman's abortion care increases the risks she faces.

13. It is inconsistent with both my medical judgment and my deeply held values to deny a patient's urgent request for time-sensitive medical care that I am qualified to provide—but that is exactly what the REMS required of me.

14. In September 2017, I was contacted by the Chief Medical Officer of

our health care system, who had apparently been informed of my request. To my knowledge, it is very unusual for the CMO to be involved in a formulary request, and I assume that my request was only elevated to this very high level because of the controversy surrounding abortion. He proposed a possible strategy to enable me to provide Mifeprex to my patients while avoiding the conflict that he expected would result from a system-wide debate on this question: namely, that I would prescribe and dispense Mifeprex as a "non-formulary drug," which the policy defines as "[a]n agent, which has not been reviewed by the [pharmacy committee] or has been reviewed and denied admission to the formulary."

15. This was a highly unusual application of our policy on non-formulary drugs, which to my knowledge is typically invoked in situations where patients admitted to our hospital need to continue a pre-established medication regimen for the short period of time that they are admitted. The policy on non-formulary drugs also expressly provides that usage of such medications will be "tracked and routinely reviewed . . . to evaluate appropriateness" by the system-level pharmacy committee—the very same committee that this strategy was designed to avoid, given the expectation of conflict over the abortion issue. Classifying Mifeprex as a non-formulary drug to be "tracked and routinely reviewed" meant that I had to continue to expend time, and put my professional reputation on the line, having discussions with leadership at my institution regarding my Mifeprex use. And, of

course, this designation meant that I could suddenly lose the ability to provide this care to my patients.

16. After gaining this temporary, precarious approval to stock and dispense Mifeprex on-site as a non-formulary drug, I next had to sign up with Danco (the manufacturer of Mifeprex) as a certified prescriber and set up an account with the drug distribution company. This was a significant ordeal in and of itself, further delaying my ability to care for my patients by approximately two months. I completed as much of the paperwork myself as I could, but setting up an account requires information (including on billing and shipping) that, as a doctor within a large health care institution, I do not have. This meant that I had to involve yet another colleague in the process—my Practice Administrator, who oversees finances, staffing, and other significant matters in our practice—and then repeatedly bother that person, who I know to be personally opposed to abortion, until it got done. If not for the REMS, I would not have had to compromise this important professional relationship in this manner.

17. I believe that the REMS has harmed my reputation among some of my colleagues by necessitating that I engage in an internal lobbying campaign to try to make Mifeprex available onsite, and necessitating the involvement of additional members of our staff in this care. For instance, I was informed about a senior leadership meeting at which a colleague raised as a "concern" that I was working

to make Mifeprex available at our facility (mentioning me by name).

18. *None* of this would have been necessary if I could simply write a prescription for Mifeprex for my patient to fill at a retail pharmacy, as I can do for virtually every other prescription drug. My colleagues do not have to expend such time and resources, or jeopardize their professional reputations, in order to prescribe other medications that are equally or less safe than Mifeprex.

19. Earlier in 2019, our health care system finally approved Mifeprex as a formulary drug. But this was no quick fix: ordering, stocking, and dispensing the medication remains a complicated, multi-stage process involving numerous staff members across our health care system. To begin, one provider from each individual clinic or hospital wishing to prescribe Mifeprex must register with the "buyer" for our health care system's central pharmacy. This entails attesting that they will oversee the prescription and dispensing of Mifeprex at their clinic or hospital site; completing the necessary materials for Danco; determining how many doses to order; and all of the correspondence and paperwork this necessitates. The central pharmacy then orders the medication to be stocked at the specific clinic or hospital.

20. In the Family Medicine clinic where I work, Mifeprex is stored under lock in our medication stock room, where we keep vaccines and other medications administered in the clinic (typically drugs administered by injection, or basic

painkillers like ibuprofen). When one of the medical assistants who works in my clinic sees that I have entered an order for Mifeprex, she goes into the medication stock room to obtain the pill and complete the special Mifeprex log, noting the serial number of the package (as required by the REMS) as well as the two-part patient ID (typically, the patient's medical records number and date of birth).

21. Having to comply with the REMS thus dramatically increases the number of people in our health care system who must be involved in the provision of Mifeprex. In addition to posing logistical complications, this heightens the risk of a violation of patient confidentiality—and perpetually threatens that a single individual who opposes abortion could delay or derail the process. By contrast, if not for the REMS, I could just electronically submit the prescription order to a pharmacy of my patient's choice and no one else would have to be involved.

22. Notably, formulary drugs are still subject to "annual" review by the system-level pharmacy committee (as compared to the "routine" review for non-formulary drugs)—which means that availability at our hospital is still subject to debate every year by a committee, the members of which change on a regular basis. My ability to include Mifeprex within my practice, and my patients' access to this vital care, remains precarious.

23. The Mifeprex REMS also requires me to provide my patients with and discuss, and for us each to sign, a "Patient Agreement Form" containing medical

information about Mifeprex dated to March 2016. This is not merely unnecessary from an informed consent perspective—it actively *undermines* my informed consent process by forcing me to discuss with my patients information that is inconsistent with my clinical approach and increasingly out-of-step with the research on Mifeprex as science moves forward. For instance, the form requires the patient's signature that, "[i]f my pregnancy continues after treatment with Mifeprex and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy." However, I (like many clinicians) treat the small percentage of patients whose pregnancies continue following use of the Mifeprex and misoprostol regimen with additional medication doses in the first instance, not surgery. This is well within the standard of care, yet not reflected in the form—to the contrary, the form suggests to patients that surgery is the *only* option in such a case. Moreover, the statement that "the treatment will not work . . . . in about 2 to 7 out of 100 women" is misleading and not how I counsel my patients about the expected efficacy of the treatment: while in some small number of cases, the regimen listed on the label will not fully complete the abortion, the treatment may very well still work – after, for instance, an additional dosage of misoprostol.

24. The Form is particularly ill-suited for my patients to whom I am prescribing Mifeprex as part of miscarriage management, as has become the standard of care. The Form does not describe the clinical circumstances of patients

experiencing pregnancy loss, and can be confusing and distressing for them. Nevertheless, because of the REMS, I still must have these patients sign the Form before I can prescribe them Mifeprex. For all of these reasons, the Patient Agreement Form interferes with my ability to practice my profession in accordance with my medical judgment.

25. I hope that more clinicians within our health care system will begin providing Mifeprex at their own hospitals and clinics as well, and thus continue to expand access to this safe and effective medication. I have had numerous conversations with like-minded colleagues to that end, including giving them advice about navigating the multi-step, time-consuming process I described above to register with both our health care system and with Danco as a prescriber and then to actually get the medication onsite. Unfortunately, these logistical hurdles caused by the REMS have proven to be a significant deterrent, and there are still only a handful of us in the health care system who prescribe Mifeprex, either for abortion care or for miscarriage management.

I declare under penalty of perjury that the foregoing is true and correct.

Executed in [redacted], on [redacted], 2021.

[redacted]

[redacted], M.D., a/k/a Jane Roe, M.D.

EXHIBIT 8

Declaration of Diana M. Pearce, Ph.D.
& Pearce Decl. Appendix

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN**
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*
***admission for pro hac vice pending*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE**
RUTH HARLOW**
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN**
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]

DECLARATION OF DIANA M. PEARCE, PH.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Diana M. Pearce, Ph.D., declares and states as follows:

I. BACKGROUND AND QUALIFICATIONS

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I provide the following facts and opinions as an expert in the field of Sociology, specifically specializing in poverty, women's welfare, and women studies in the United States. I hold an M.S.W. and a joint Ph.D. in Social Work and Social Science (Sociology) from the University of Michigan. I am currently the Scholar in Residence at the Center for Women's Welfare at the School of Social Work at the University of Washington, after serving as the Founder and Director of the Center for 18 years. For more than two decades, I have been on the faculty of the School of Social Work as a Senior Lecturer (now Senior Lecturer Emerita), as well as an affiliate of the Gender, Women and Sexuality Studies department and the West Coast Poverty Center, all at the University of Washington. For over 40 years, I have conducted research and published on the topics of poverty and women's welfare in peer-reviewed sociology and poverty journals. Most famously, I coined the term "the feminization of poverty,"[1] which became one of the ten themes of the Beijing Conference on Women in 1995, as well as the subject of countless articles and books.

[1] Diana M. Pearce, *The Feminization of Poverty: Women, Work and Welfare*, 11 Urb. & Soc. Change Rev. 28 (1978).

I have also authored numerous reports, including for the U.S. Department of Labor and the U.S. Civil Rights Commission.

3. Since 1996, I have been the creator and principal investigator of the Self-Sufficiency Standard (the "Standard"), which measures the amount of income necessary for different family types to meet basic needs without public subsidies or private/informal assistance. Since then the Standard has been calculated for 41 states.[2]

4. I have presented my research on poverty at numerous professional conferences and governmental briefings, including presentations to the U.S. Department of Health and Human Services and the U.S. House of Representatives. I also testified twelve times before the U.S. Congress. I have received various awards for my work and research, including:

- National Association of Social Workers, Presidential Award for Leadership in Research (presented at NASW Conference, The Feminization of Poverty Revisited) (2013)
- Wider Opportunities for Women, Setting the Standard (Lifetime Achievement) Award (2003)
- Workforce Development Council of Seattle-King County, for Visionary Research on Family Self-Sufficiency (2003)
- Society for Applied Sociology, Sociological Practice Award (2003)

[2] For all data and reports relating to and a general explanation of the Standard, see generally Self-Sufficiency Standard, http://www.selfsufficiencystandard.org/ (last visited Apr. 7, 2021).

5. A true and correct copy of my curriculum vitae is attached as Exhibit H-1 to this declaration.

II. THE IMPACT OF THE RISK EVALUATION AND MITIGATION STRATEGY (REMS) FOR MIFEPREX ON WOMEN SEEKING ABORTION CARE

6. I have been asked to evaluate the impact of the Mifeprex REMS on women in the United States seeking abortion care.[3] I understand that under the Mifeprex REMS, a patient cannot obtain the medication by prescription at a retail pharmacy or by mail; they must receive it at a clinic, medical office, or hospital from a clinician who has prearranged to stock and dispense Mifeprex. I understand that these requirements deter or prevent a significant number of health care providers, such as Dr. Graham Chelius on Kaua‘i, from prescribing medication abortion, and, as a result, some patients have to travel further distances or make an entirely unnecessary trip in order to access time-sensitive abortion care. I understand further that the REMS prevents medication abortion patients who have been evaluated and counseled via telemedicine from picking up their prescription at their local pharmacy or obtaining their mifepristone prescription by mail without even having to leave home, forcing such patients instead to make a trip to a REMS-certified provider just to pick up the pill and sign a form.

[3] I use “women” here as a shorthand for patients who need abortion care, but note that patients who are gender non-binary or transgender also utilize these services.

7. Data demonstrate that the overwhelming majority of abortion patients are low-income and struggle to make ends meet. As an expert in poverty and women's welfare who has studied the barriers that affect low-income women's access to health care, I know that low-income people find it extremely difficult just to afford their basic household needs, let alone unplanned emergency expenses like abortion. In my expert opinion, by requiring patients to make additional and/or lengthier trips to get a medication abortion, the Mifeprex REMS increases the costs and logistical burdens of accessing care—including missed work, transportation and child care costs—to such a degree that they significantly delay or entirely prevent women from accessing abortion care. Even for those who are ultimately able to access care, the resources and other hurdles that the REMS force women to navigate often require significant sacrifices for patients and their families that threaten patients' privacy and economic stability, including by jeopardizing their employment or housing, forcing patients to forgo other necessary expenses like food or other medical care, and increasing the risk of domestic violence.

A. Many Abortion Patients Cannot Afford to Meet Their Basic Needs.

8. The vast majority of women seeking abortion care have low incomes. In 2014, the most recent year for which data are available, half (49%) of women seeking abortions in the United States had incomes at or below the U.S. Official Poverty Measure (OPM), which for 2014 was $11,670 annually for a single person

or $19,790 for a family of three (in the contiguous U.S.).[4] Another quarter (26%) of U.S. abortion patients had incomes between 100 and 200% of the OPM in 2014.[5] In other words, based on the OPM, three out of four abortion patients are poor or very low-income.[6]

9. But it is likely that this statistic actually undercounts the percentage of abortion patients with inadequate income to meet their basic needs, because the OPM is based on a flawed and outdated methodology and set of assumptions. The OPM was developed decades ago and assumes that a family's total budget is three times what they spend on food—reflecting average American family expenditure patterns of the mid-1950s. However, household expenditure patterns have changed significantly since then. For instance, the cost of food has increased much less over

[4] Jenna Jerman, Rachel K. Jones & Tsuyoshi Onda, Guttmacher Inst., Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008 1, 7 (2016), https://www.guttmacher.org/report/characteristics-us-abortion-patients-2014; *Prior HHS Poverty Guidelines and Federal Register References*, U.S. Dep't of Health & Hum. Servs., https://aspe.hhs.gov/prior-hhs-poverty-guidelines-and-federal-register-references (last visited April 7, 2021). For 2021, the amounts are $12,880 for a single person and $21,960 for a family of three. *2021 Poverty Guidelines*, U.S. Dep't of Health & Hum. Servs.: ASPE (last updated Jan. 26, 2021), https://aspe.hhs.gov/2021-poverty-guidelines.

[5] Jerman, Jones & Onda, *supra* note 4, at 1, 7.

[6] *Id.* Because these statistics are drawn from surveys of patients who received an abortion, they do not account for poor or low-income patients who wanted to have an abortion but were prevented from accessing one because of financial or other barriers to access. *Cf., e.g.*, Sarah C.M. Roberts et al., *Out-of-Pocket Costs and Insurance Coverage for Abortion in the United States*, 24 Women's Health Issues e211, e215 (2014), https://www.sciencedirect.com/science/article/abs/pii/S1049386714000048 (in longitudinal study of abortion patients at 30 facilities across the country, more than half reported that the need to raise money delayed access to care).

the past decades than almost all other basic expenses, while other costs have increased substantially (housing, health care, taxes). Moreover, the OPM does not account for geographic variation in costs or for variations in family type (such as by children's ages), and it does not explicitly reflect basic needs like child care, taxes, health care, and transportation.[7]

10. A more accurate measure of income inadequacy is the Self-Sufficiency Standard, which my colleagues and I first developed two decades ago to address gaps and deficiencies in the federal poverty measures. The Self-Sufficiency Standard describes the minimally adequate income that a family of a certain composition in a given place needs to meet their basic needs, without public or private assistance. It is tailored to reflect the minimum actual costs of housing, child care, food, transportation, health care, miscellaneous expenses, taxes, and tax credits for 719 family types in every county in a given state. The Standard additionally reflects cost

[7] Increasing recognition of the OPM's shortcomings led Congress in the 1990s to direct the National Academies of Sciences, Engineering and Medicine to undertake a wide-ranging study of the measure. *See* Nat'l Rsch. Council, Measuring Poverty: A New Approach xv, 2–3 (Constance F. Citro & Robert T. Michael, eds. 1995), https://www.nap.edu/download/4759#. The study and resulting report spurred a number of experimental measures piloted by the U.S. Census Bureau, and, in 2010, the Bureau adopted the Supplemental Poverty Measure (SPM). *See* Liana Fox, U.S. Census Bureau, The Supplemental Poverty Measure: 2019 (2020), https://www.census.gov/library/publications/2020/demo/p60-272.html. Although the SPM addresses some of the problems with the OPM, such as varying housing costs by Census region, it does not consider the substantial variation in housing costs within the four Census regions, and it either fails to or inadequately addresses the other flaws discussed above. In particular, the SPM methodology does not address the most serious shortcoming of the OPM— that it seriously underestimates the total cost of basic needs—and thus like the OPM, the SPM is likewise much too low, everywhere and for every family type.

differentials due to the age of children; thus, families with children below school age requiring full-time child care will have a higher Standard than those with older or no children. Whenever possible, the amount for a given need is based on the amount of financial assistance that the government (federal or state) has deemed minimally adequate for that basic need (such as housing, child care, or food expenses).[8]

11. We have found that a substantial percentage of people across the country—and far more than are captured by the OPM—do not have incomes sufficient to meet their basic needs.[9] (This is true even though the vast majority of households with incomes below the Standard have at least one worker in them.[10]) The Standard is higher than the OPM in every jurisdiction for which we have

[8] For housing, the Standard uses the U.S. Department of Housing and Urban Development Fair Market Rents, which set the maximum rent allowed for Section 8 voucher (housing assistance) recipients; for child care costs, the Standard uses the maximum amount set by the state for reimbursement for those receiving child care assistance (minus child care copayments); and for food costs, the Standard uses the U.S. Department of Agriculture's "Low-Cost" Food Plan, which only covers the cost of basic groceries, with no allowance for any take-out or restaurant food. L. Manzer & A. Kucklick, Ctr. for Women's Welfare, Technical Brief: The Self-Sufficiency Standard 2021 Update (2021) (available upon request from the Center for Women's Welfare, University of Washington School of Social Work, www.selfsufficiencystandard.org).

[9] When calculating income inadequacy compared to the Standard, we consider all cash resources available to a household, including cash assistance, such as Temporary Assistance for Needy Families (TANF) or Supplemental Security Income (SSI). It should be noted, however, that the income limits for means-tested cash assistance are very low (often near or even below the OPM), and thus are never sufficient to bring a family up to their Self-Sufficiency Standard.

[10] *See, e.g.*, Diana M. Pearce, Ctr. for Women's Welfare, Overlooked and Undercounted 2018: Struggling to Make Ends Meet in Colorado, at vi (2018), http://www.selfsufficiencystandard.org/sites/default/files/selfsuff/docs/CO18_Demo_Web.pdf.

calculated it—sometimes significantly higher.[11] This is especially true for families—which is notable here since, nationwide, about 60% of women seeking an abortion have at least one child.[12]

12. In fact, the Self-Sufficiency Standard for a family consisting of one adult and one infant exceeds *200% of the OPM* in 92% of counties in the 31 states for which we have current Standard data and in every single county in 20 states. And the gaps are similarly stark for other family types.[13] In other words, given that the Standard is a bare-bones budget, it is clear that in the vast majority of counties in most states, abortion patients with incomes living up to 200% of OPM still lack the minimum income necessary to afford even their basic household needs.

13. My research in numerous states to determine the characteristics of households most likely to have income below the Self-Sufficiency Standard further reinforces the existing data showing that most abortion patients struggle to make ends meet. As noted, a majority of abortion patients are mothers,[14] and

[11] The states with current Standard data included in this analysis are: AL, AZ, CA, CO, CT, FL, GA, HI, IL, IN, KS, MA, MD, MI, MN, MO, NC, NJ, NV, NY, OK, OR, PA, SC, TN, TX, UT, VA, WA, WI, and WY. Data on file with the author.

[12] *Abortion Surveillance — United States, 2018*, Ctrs. for Disease Control & Prevention, at Table 7 [hereinafter "*CDC Abortion Surveillance*"], https://www.cdc.gov/mmwr/volumes/69/ss/ss6907a1.htm#T7_down (last updated Nov. 7, 2020).

[13] For a family of one adult and one preschooler, the Standard exceeds 200% of the OPM in 88% of counties; for a family with one adult, one preschooler, and one school-aged child, in 83% of counties; and, for a family with two adults, one preschooler, and one school-aged child, in 84% of counties.

[14] *CDC Abortion Surveillance*, *supra* note 12, Table 7.

approximately 85% are unmarried.[15] Moreover, 60% identify as people of color, including 53% identifying as Black or Hispanic.[16] My colleagues and I have uniformly found that these are the very populations that are statistically more likely than other demographic groups to live below the Standard.

14. For example, the percentage of Black households with incomes below the Standard is on average double the percentage of white households with incomes below the Standard; the percentage of Latinx households is 2.5 times the percentage of white households; and the percentage of single-mother families with incomes below the Standard is 2.2 times that of married couples with children.[17] This is particularly true for single mothers of color: on average, almost three out of four (74%) Black single mothers, and almost four out of five (79%) Latina single mothers, have incomes below the Standard.[18]

---

[15] *Id.* at Table 6, https://www.cdc.gov/mmwr/volumes/69/ss/ss6907a1.htm#T6_down.

[16] *Id.* at Table 5, https://www.cdc.gov/mmwr/volumes/69/ss/ss6907a1.htm#T5_down; *see also* Jerman, Jones & Onda, *supra* note 4, at 1, 5.

[17] Based on an analysis of Standard data and demographic reports for California (2019), Colorado (2016), Connecticut (2017), Maryland (2015), New York City (2019), New York State (2019), Pennsylvania (2017), Washington (2013), and Wyoming (2010–2014). Data on file with the author and/or available on the Standard website, in individual reports. *See Self-Sufficiency Standard by State*, Self Sufficiency Standard, http://www.selfsufficiencystandard.org/self-sufficiency-standard-state (last visited Apr. 8, 2021); *Research and Resources: Demographic Reports*, Self Sufficiency Standard, http://www.selfsufficiencystandard.org/node/30 (last visited Apr. 8, 2021).

[18] In every state for which we have performed these demographic analyses, at least 65% of Black single mothers and 74% of Latina single mothers had incomes below the Standard, compared to an average of 52% of white single mothers. See resources listed above, *supra* note 17.

15. To further illustrate this concept, consider Kaua'i. On that island, where Dr. Chelius's patients live, the 2020 Self-Sufficiency Standard—the *minimum* income necessary for basic subsistence, based largely on government reimbursement rates—for a single adult caring for one school-aged child and one preschooler was nearly 1.75 times the median household income for single-mother households in Kaua'i, and more than triple the 2020 OPM for a family of three.[19] For a single adult caring for one infant, the Standard was 1.8 times higher than the median income for single mothers in Kaua'i, and more than four times the 2020 OPM for a family of two.[20] Thus, many single-mother households in Kaua'i that would not be classified as poor or low-income according to the OPM are in fact struggling to afford basic household needs.

16. Kaua'i is not an outlier. I analyzed the monthly basic needs budget for families with one adult and one preschooler in the least expensive county, median county, and county with the largest city in eight representative states across the

[19] *Compare Hawaii Self-Sufficiency Standard Table, 2020*, at By County tab, Table 3, cell L71 (2020) [hereinafter "*Hawaii Standard 2020*"], http://www.selfsufficiencystandard.org/node/50 (Self-Sufficiency Standard of $69,224), *with* U.S. Census Bureau, *Table S1903: Median Income in the Last 12 Months*, https://data.census.gov/cedsci/table?q=S1903&tid=ACSST1Y2019.S1903 (filter by "Browse Filters: Geography," "Geography: County," "Within (State): Hawaii," and select "Kauai County, Hawaii) (last visited April 7, 2021) (median income of $39,422 for "Female householder, no spouse present" and "With own children under 18 years"), *and 2020 Poverty Guidelines*, U.S. Dep't of Health & Hum. Servs.: ASPE (last updated Jan. 21, 2020), https://aspe.hhs.gov/2020-poverty-guidelines (2020 OPM of $21,720).

[20] *Compare Hawaii Standard 2020*, *supra* note 19, at By County tab, Table 3, cell C71 (Self-Sufficiency Standard of $70,788), *with* U.S. Census Bureau, *Table S1903*, *supra* note 19 (median income of $39,422), *and 2020 Poverty Guidelines*, *supra* note 19 (2020 OPM of $17,240).

country, all of which have statewide poverty rates (according to the OPM) similar to either the national average or the average for their geographic region.[21] In every county in every state considered in this analysis, a full-time minimum wage worker[22] is unable to afford the minimum needs for their family. In all eight states, one adult with a preschool-aged child in the least expensive county in the state (*i.e.*, the county with the *lowest* Standard) needs at least 36% more than a full-time minimum wage income (Santa Cruz County, AZ) and as much as two or more times the minimum wage (Uvalde County, TX, and Person County, NC), just to afford their family's basic needs. For those living in the largest city in each of these states, the deficit is even more substantial: in Chicago (Cook County, IL), a single mother with a preschooler needs to earn almost twice the minimum wage, while in Charlotte, NC (Mecklenburg County), she needs to earn at least 3.6 times the minimum wage, just to meet her basic needs. These families are already forced to make sacrifices or economic trade-offs just to scrape by; *any* added expense, no matter how small, can be destabilizing, potentially forcing them to forgo basic needs like food, rent, or

[21] States used in this analysis are those (a) with statewide poverty rates closest to the national rate or to the average rate for states in their Census region, based on data from the U.S. Census Bureau, and (b) for which current Self-Sufficiency Standard data (2021) was available. *See* Exhibit H-2 (summarizing Standard data for all 8 states).

[22] The Standard assumes full-time work (40 hours per week). Thus, I am evaluating whether full-time work at the state (or local) minimum wage will be enough to meet the cost of basic needs in the Standard for this family type in each place.

medical care.[23]

17. Key economic trends indicate that American families may be facing even more challenges in the future. For example, in every state in which my colleagues and I have tracked the Standard over the last two decades, the cost of basic needs has been rising faster than income, even during the Great Recession and the subsequent Recovery.[24] In addition, the economic precarity of many working families across the country has only been amplified by the current economic recession relating to the COVID pandemic. While the data showing the full extent of the economic impact of the pandemic is not yet available, and uncertainty remains due to new surges in COVID cases, the widespread job losses and staggeringly high rates of unemployment experienced so far already have taken their toll, with large

[23] For many families, public assistance will be inadequate to fill these gaps. For example, as its name suggests, the Temporary Assistance for Needy Families Program (TANF) is not designed to be an ongoing source of income for working families; although work is required to maintain eligibility, even working part-time is likely to result in an income too high to maintain eligibility for TANF. And while in-kind benefits such as SNAP (food stamps), child care assistance, and housing assistance are meant to help low-wage workers, only a minority of eligible families actually receive those benefits. *See, e.g.*, Gov't Accountability Office, Child Care: Subsidy Eligibility and Receipt, and Wait Lists – Briefing to Senate Comm. on Health, Educ., Labor & Pensions and House Comm. on Educ. & Labor, GAO-21-245R, at 12 (2020), https://www.gao.gov/assets/gao-21-245r.pdf (only 14% of children eligible for child care assistance under federal standards, and only 22% of those eligible under state rules, actually receive such assistance in an average month); G.T. Kingsley, Urban Institute, Trends in Housing Problems and Federal Housing Assistance3 (2017), https://www.urban.org/sites/default/files/publication/94146/trends-in-housing-problems-and-federal-housing-assistance.pdf (only about one in five low-income renters with housing needs received assistance in 2015).

[24] For example, see Standard Reports for Colorado, Connecticut, Indiana, Maryland, Michigan, New York, New York City, North Carolina, Ohio, Oregon, South Carolina, Washington, Wisconsin, and Wyoming, all available at *Self-Sufficiency Standard by State*, *supra* note 17.

numbers of families citing serious economic impacts and concerns for the future.[25] These losses have disproportionately affected single mothers, particularly women of color, and other households that had inadequate income to meet their basic needs even before the recession.[26]

18. In sum, in considering the impact of the Mifeprex REMS on access to abortion nationwide, it is important to recognize that the vast majority of abortion patients—likely even *more* than the 75% of patients with incomes at or below 200% OPM—are already unable to afford their and their families' basic needs. For these patients, the unexpected, emergency expenses associated with traveling for abortion care—whether to another county, city, or state, or even to a second local health care facility—presents a serious hardship or is entirely impossible.

B. The Mifeprex REMS Imposes Significant Costs and Burdens on Medication Abortion Patients.

19. Abortion access is very limited in the United States. Approximately 90

[25] J. Horowitz et al., *A Year Into the Pandemic, Long-Term Financial Impact Weighs Heavily on Many Americans*, Pew Rsch. (Mar. 5, 2021), https://www.pewresearch.org/social-trends/2021/03/05/a-year-into-the-pandemic-long-term-financial-impact-weighs-heavily-on-many-americans/ (finding that 40% of adults say they or someone in their household lost a job or wages during the pandemic, and half of those who did so are still earning less than before the pandemic).

[26] *See id.* (finding that, during the pandemic, Black and low-income workers are more likely to have incurred debt or put off paying household bills due to lost income); A. Barroso & R. Kochhar, *In the pandemic, the share of unpartnered moms at work fell more sharply than among other parents*, Pew Rsch. (Nov. 4, 2020), https://www.pewresearch.org/fact-tank/2020/11/24/in-the-pandemic-the-share-of-unpartnered-moms-at-work-fell-more-sharply-than-among-other-parents/ (finding steepest declines among Black and Hispanic single mothers and single mothers with young children).

percent of U.S. counties lack an abortion clinic, and, nationwide, 38% of women of reproductive age live in those counties.[27] A survey of a nationally representative sample of more than 8,000 abortion patients found that the average distance traveled to reach the clinic was 68 miles round-trip.[28] In a majority of states, at least one in five women of reproductive age lives more than 50 miles from the nearest clinic.[29] While rural women are most likely to face significant travel distances,[30] women in many cities must also travel significant distances to obtain abortion care: for instance, a 2018 study characterized 27 major U.S. cities as "abortion deserts" because they did not have a publicly advertised facility that provides abortions within 100 miles.[31]

---

[27] Rachel K. Jones & Jenna Jerman, *Abortion Incidence and Service Availability in the United States*, *2014*, 49 Persp. on Sexual & Reprod. Health 17, 20 (2017), https://onlinelibrary.wiley.com/doi/epdf/10.1363/psrh.12015. Today, 95% of abortions are performed in clinics (rather than doctors' offices or hospitals). *Id.* at 17.

[28] 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/.

[29] 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 live more than 50 miles away, including two where a majority live more than 150 miles from the nearest provider).

[30] *See, e.g.*, Nicole E. Johns et al., *Distance Traveled for Medicaid-Covered Abortion Care in California*, 17 BMC Health Serv. Res. 287, 294 (2017), https://doi.org/10.1186/s12913-017-2241-0 (more than half of rural women in California traveled more than 50 miles to obtain an abortion); Bearak et al., *supra* note 29, at e497 (identifying swath of rural counties in the middle of the United States with travel distances of more than 180 miles to nearest abortion clinic).

[31] 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/.

20. I understand that the Mifeprex REMS increases the distance that many women must travel to obtain a medication abortion, both by diminishing the number of medication abortion providers across the country (thus increasing the distance or number of trips patients must make to access care), and by preventing medication abortion providers from delivering mifepristone care to their eligible patients using telemedicine and mail (*i.e.*, but for the REMS, those patients would not have to travel at all to get the care they need).

21. As detailed below, the costs and burdens associated with increased travel and/or multiple trips to obtain an abortion typically include transportation, child care, and missed work, and may also include lodging, increased food costs (while traveling), and other unexpected expenses. There are also nonfinancial costs, as the logistics and time associated with travel, and the need to raise money for travel and associated costs, will often require the patient to share the fact of her abortion with people, such as household members and employers, whom she otherwise would not wish to tell—which may put her at risk for domestic violence or jeopardize her employment.

22. In my expert opinion, the overwhelming majority of people seeking abortions nationwide who have incomes too low to meet their basic needs—at *minimum*, three out of four abortion patients—suffer significant harm as a result of these added costs and burdens. Many are delayed in accessing this time-sensitive

care while they raise funds and make travel and logistical arrangements; some are blocked from obtaining an abortion at all because they cannot afford and navigate these costs and complications, or because they cannot safely share their abortion decision with household members or employers. Even those who are able to obtain an abortion despite these hurdles will have to make harmful trade-offs to do so—such as forgoing groceries or other medical care for themselves or their families, failing to pay bills including those for heat or rent, which puts the family at risk of losing their utilities or housing, or otherwise incurring debts that could have long-term consequences for household stability—or be forced to compromise their privacy and safety to access care.

Travel and Transportation

23. The additional travel costs necessitated by the REMS in order to access a medication abortion impose substantial burdens for low-income women. Even local trips of relatively short distances can present significant financial and logistical challenges for low-income women, who—as discussed above—are typically already struggling to afford basic household needs. And those costs and burdens are compounded for patients who live a considerable distance from the nearest medication abortion provider and who may have to incur significant financial costs for transportation, time off from work, child care, and potentially meals away from home, and lodging in order to access care.

24. For people with incomes below the minimum basic needs budget for their area, *any* added expenses—like refilling a gas tank, or taking a relatively short taxi ride—can stretch already strained and overextended budgets. The logistical burdens of arranging a trip to a REMS-certified provider can be especially challenging for those living in the majority of places in the United States with limited or essentially no public transportation options, particularly given that 9% of all households in the U.S. and 24% of households with incomes below the OPM do not have a vehicle, or have access to a vehicle.[32] Even if a low-income woman has access to a car, it may be shared among multiple people, which can limit access in practice, thus delaying care or forcing patients to disclose their abortion to others.

25. These burdens are compounded for those women who live farther from a REMS-certified provider and who may have to travel outside their county or state to access care. Cars owned by low-income households are older on average[33] and therefore less dependable for long journeys. And, for those without access to a

[32] *See* N. McGuckin & A. Fucci, U.S. Dept. of Transp., Summary of Travel Trends 2017 National Household Travel Survey 60, at Table 17, (2018) [hereinafter "NHTS 2017 Summary"], https://nhts.ornl.gov/assets/2017_nhts_summary_travel_trends.pdf; U.S. Dep't of Transp., Fed. Highway Admin., FHWA NHTS BRIEF 2014: Mobility Challenges for Households in Poverty 2. (2014), https://nhts.ornl.gov/briefs/PovertyBrief.pdf.

[33] NHTS 2017 Summary, *supra* note 32, at 8, 20; *see also* Jenna Jerman et al., *Barriers to Abortion Care and Their Consequences For Patients Traveling for Services: Qualitative Findings from Two States*, 49 Perspectives on Sexual & Reprod. Health 95, 98 (2017) (in qualitative study of abortion patients in New Mexico and Michigan who crossed state lines or traveled long distances, factors including "limited access to safe and reliable transportation, or the need to use multiple means of transport[] significantly increased the time it took women to travel even relatively short distances" to access abortion care).

private car, bus or other transportation options between cities may be limited or inaccessible. For example, for a patient in Phillipston, MA,[34] there are abortion providers approximately 30 miles away in Worcester, MA,[35] and Keene, NH. But given limited public transportation options, traveling to Worcester would take at minimum 4 hours and three bus transfers, at an estimated round-trip cost of $42.50[36]; traveling to Keene, NH, would require five transfers and more than a day of travel.[37] For a patient in Cullowhee (Jackson County), NC, there are no public transportation options available to the nearest provider approximately 50 miles away in Asheville;

[34] With the exception of Kaua'i, Hawai'i, all other locations used to provide examples of travel distances, routes, and costs in this section are drawn from the same subset of counties in states with poverty rates similar to regional and national averages listed in Exhibit H-2.

[35] All distances to nearest providers are based on a search of publicly listed abortion clinics via Planned Parenthood, https://www.plannedparenthood.org/ (last visited Apr. 8, 2021), and *Find a Provider*, National Abortion Fed'n, https://prochoice.org/patients/find-a-provider/ (last visited Apr. 8, 2021). Driving distances in this section are estimated using Google Maps, assuming uncongested travel times. Bus, train, and flight fares assumed travel within two weeks of search.

[36] *See MART Trip Planner*, Montachusetts Reg'l Trans. Auth., http://www.mrta.us/trip-planner (search start: "Phillipston, MA," and finish: "Worcester, MA"). The Athol Link bus service departs Phillipston approximately every 90 minutes between 5:45 a.m. and 6:00 p.m., Monday through Friday. Patients would need to transfer at the Gardner City Hall stop to the Wachusett Shuttle line, which, at the time of search, was operating on a limited schedule of only four departures per day (6:05 a.m., 8:20 a.m., 1:05 p.m., and 6:05 p.m.). Patients would then need to transfer again at the MART Intermodal Transportation Center to the Clinton-Worcester Commuter Shuttle (commuter line, only running in morning hours) or the Worcester Shuttle (only three departures per day) for service to downtown Worcester. For full route schedules and fares, see *Routes and Schedules*, Montachusetts Reg'l Trans. Auth., http://www.mrta.us/routes-schedules (last visited Apr. 9, 2021), and *Fares and Passes*, Montachusetts Reg'l Trans. Auth, http://www.mrta.us/farespasses (last visited Apr. 9, 2021). Patients would also need to arrange transportation from home to the departure station and from the arrival station to the clinic.

[37] *See MART Trip Planner*, *supra* note 36. Although my search identified other clinics within 50 miles of Phillipston, travel by public transportation was similarly complicated for all options, involving multiple transfers and multiple-hour trips.

she would have to take a taxi all the way to the outskirts of the city to reach the closest bus stop, at a cost of $140–170.[38] For the families living below the Self-Sufficiency Standards for those states, these added expenses and lengthy travel time—not to mention the time and effort necessary to navigate multiple bus schedules and transfers in potentially unfamiliar locations—may be insurmountable.

26. Furthermore, routes and departure times are often very limited—even more so now, as some services reduced routes during the pandemic and have not yet resumed full service. If available arrival times do not align with available appointment times, even trips of only moderate distance may turn into more expensive cab rides,[39] or require overnight stays, requiring lodging and increasing child care costs and time away from work.

27. The burdens continue to increase for the sizeable percentage of women traveling especially long distances of 100 miles or more each way to access abortion care,[40] such as those in Quartzsite, AZ (La Paz County), who must travel

[38] *See* Rome2Rio, https://www.rome2rio.com/map/Asheville/Cullowhee (last visited Apr. 9, 2021).

[39] For example, a taxi between Phillipston and Worcester could cost approximately $110 one way, or $220 round-trip. *See* Taxi Fare Finder, https://www.taxifarefinder.com/ (last visited Apr. 12, 2021) (searching for "Phillipston, Massachusetts," to "Worcester, Massachusetts," and selecting "Cheapest" filter).

[40] *See, e.g.*, Bearak et al., *supra* note 29 (majority of women of reproductive age in North Dakota and Wyoming and one in five women in Alaska, Idaho, Kansas, Missouri, Montana, New Mexico, and South Dakota lived more than 100 miles from the nearest provider).

approximately 125 miles each way to reach a provider in Phoenix, AZ,[41] or Dalhart (Dallam County), TX, who must travel 200 miles each way to Lubbock, TX.[42] In extreme cases, such as for patients living in Hawai‘i or in other states with island populations (such as Alaska, Maine, North Carolina, and Florida), air travel may be required to access in-person abortion care. For example, in Hawai‘i, I understand that there are no clinics offering abortion care on the islands of Kaua‘i, Hawai‘i, Lana‘i, Moloka‘i, and Ni‘ihau, necessitating inter-island travel to O‘ahu to reach the nearest abortion provider. Since these arrangements are often made within a short timeframe, the costs tend to be higher than for long-planned travel. For example, the lowest round-trip ticket to O‘ahu (bought for travel within two weeks of purchase) was $178 for Kona, Lihu’e, or Hilo, according to Kayak.com.[43] On top of flight costs, abortion patients would also need to pay for ground transportation to and from the airport and/or overnight parking. For those living on Hawai‘i, the price of a taxi to or from the Hilo airport can run from $12 for people living in Hilo to $104 for

[41] Approximately 2 hours by car or bus ($56–62 round-trip, depending on how many days in advance of travel reservation is made, with only 4:00 a.m. departures and 10:30 p.m. returns available). *See Book A Trip*, Greyhound, https://www.greyhound.com/en (last visited Apr. 11, 2021). Clinics in El Centro, CA, and Coachella, CA, are similar distances by car, but options by bus take much longer and are more expensive.

[42] Approximately 3 hours by car. There is no bus service directly from Dalhart. Patients would have to arrange transportation to Dumas, TX (approximately 35 miles away), for bus service to Lubbock (at least 3.5–5 hours, depending on schedule), at a total round-trip cost of $200–280, including a taxi from Dalhart to Dumas. *See* Greyhound, *supra* note 41; Rome2Rio, https://www.rome2rio.com/map/Dalhart/Lubbock (last visited Apr. 11, 2021).

[43] Kayak.com, http://www.kayak.com (last visited April 7, 2021).

people living in Honoka'a.[44] Additionally, the cost of public transportation once on O'ahu is $5.50 per day. Thus, for a woman from Honoka'a traveling to Honolulu for abortion care, the cost of ground transportation alone (in both places) can exceed $219.[45] In addition, for many low-income women, particularly those for whom English is a second language and/or non-citizens, air travel may pose psychological and emotional hurdles, as it requires security checks, identification that may not be regularly needed, and simply the unfamiliarity of airplane travel.

28. Finally, for those who have to travel long distances or inter-island—such as patients in Hawai'i, Buffalo (Dallas County), MO (320 miles round-trip to Kansas City, KS), or Dalhart, TX (400 miles round trip to Lubbock)—travel for abortion may require overnight lodging,[46] for example, because of limited bus

[44] *Taxicab*, Hawaii.gov: Hilo Int'l Airport, http://airports.hawaii.gov/ito/getting-to-from/ground-transportation/taxicab (last visited April 7, 2021). For patients with cars, the cost of parking at the Hilo airport is $15 per day. *Parking*, Hawaii.gov: Hilo Int'l Airport, http://airports.hawaii.gov/ito/getting-to-from/parking/ (last visited April 7, 2021). Like many other places in the United States, Hawai'i has poor public transportation options, especially outside of O'ahu, and visitors to the counties of Hawai'i and Kaua'i, for example, are strongly urged to rent a car or use taxis for local transportation. *See* Sheila Beal, *What are the public transportation options in Hawaii*, Go Visit Hawaii (Oct. 23, 2017), https://www.govisithawaii.com/2017/10/10/what-are-the-public-transportation-options-in-hawaii/; *Transportation Rankings*, U.S. News, https://www.usnews.com/news/best-states/rankings/infrastructure/transportation (last visited April 7, 2021) (ranking the state of Hawaii 40th in terms of transportation infrastructure).

[45] *Adult Fare*, The Bus: City and County of Honolulu, http://www.thebus.org/Fare/Adultfare.asp (last visited April 7, 2021).

[46] *See, e.g.*, Caitlin Gerdts et al., *Impact of Clinic Closures on Women Obtaining Abortion Services After Implementation of a Restrictive Law in Texas*, 106 Am. J. Pub. Health 857, 861–63 (2016) (in study of Texas abortion patients whose nearest abortion clinic had closed as a result of a 2013 law, 16% reported having to stay overnight to access abortion care).

schedules, to accommodate early morning appointments, to obtain the least expensive bus or flight ticket, or if the round-trip distance is too far to travel in a single day.[47] Such costs are typically higher if reservations must be made just a few days or weeks ahead of time. According to a discount website, the cost of lodging starts around $83 in Honolulu, $43 in Lubbock TX, and $49 in Kansas City, KS.[48]

29. Especially for women already struggling to make ends meet, the added costs and logistical burdens of arranging transportation to a REMS-certified provider can be onerous, if not insurmountable.

Missed Work

30. Traveling to pick up a pill in person at a hospital, clinic, or medical office instead of receiving it by mail at home, or traveling to a second health care facility because the provider who diagnosed a patient's pregnancy cannot write them a prescription for Mifeprex, also may interfere with patients' work schedules. Women who have to travel long distances to reach a REMS-certified prescriber may

[47] For example, there is no direct bus service out of Buffalo, MO. To reach Kansas City, KS, a patient would first need to figure out how to get to Springfield, MO, 30 miles away. From there, she could take a Greyhound bus to Kansas City, MO, and then a shuttle to Kansas City, KS, at a cost of $62–104 round-trip (depending on how many days in advance she makes the reservation), not including the cost of getting to Springfield and back. In addition, there is only one bus per day between Springfield and Kansas City, departing at 2:15 p.m., and arriving at approximately 6:00 p.m. Accordingly, she would also likely need to travel the day before her appointment and stay overnight. *See* Greyhound, *supra* note 41 (no results for "Buffalo, MO"; results for travel to Kansas City, MO, from Springfield). Alternative options from Springfield include, *e.g.*, a 4.5-hour bus at a cost of $130 round-trip to St. Louis, MO, or a 3.5-hour bus ride each way at a cost of approximately $72–96 round trip to Tulsa, OK, which would also likely require an overnight stay. *Id.*

[48] *See* Hotels.com, https://www.hotels.com/ (last visited Apr. 11, 2021).

miss multiple days of work. Especially for low-income workers, the burdens associated with arranging time off work can result in delayed care, lost income, and even threats to job security.

31. About 40% of women workers in the United States have no paid time off.[49] Among low-wage workers (the bottom 25%), 93% lack paid family leave and 49% lack paid sick leave[50]; and almost two-thirds of workers in jobs that do not require a college degree lack paid personal days.[51] For part-time workers,[52] 92% lack paid family leave, three-quarters have no paid sick leave, and two-thirds lack any paid vacation or holidays.[53] For those without paid time off, any time away from work in order to access abortion care translates into lost wages. According to one study, the mean wages lost as a result of traveling for abortion care because of missed

[49] Cynthia Hess et al, Inst. for Women's Pol'y Res., The Status of Women in the States: 2015, at 88 (2015), https://iwpr.org/wp-content/uploads/2020/08/R400-FINAL-8.25.2015.pdf.

[50] Pronita Gupta et al., Paid Family and Medical Leave is Critical for Low-wage Workers and Their Families 1 (Dec. 2018), https://www.clasp.org/publications/fact-sheet/paid-family-and-medical-leave-critical-low-wage-workers-and-their-families.

[51] Gregory Acs & Pamela Loprest, Urb. Inst., Employers in the Low-Skill Labor Market, Brief No. 2: Low-Skill Jobs, Work Hours, and Paid Time Off 4 (2008), https://www.urban.org/sites/default/files/publication/32211/411802-Low-Skill-Jobs-Work-Hours-and-Paid-Time-Off.PDF.

[52] Twenty-five percent of women workers are employed in a part-time position. *Economics Daily: Percentage of Employed Women Working Full Time Little Changed Over Past 5 Decades*, U.S. Bureau of Lab. Statistics (Dec. 1, 2017), https://www.bls.gov/opub/ted/2017/percentage-of-employed-women-working-full-time-little-changed-over-past-5-decades.htm?view_full.

[53] Gupta, *supra* note 50, at 1; Hess et al, *supra* note 49, at 89.

work was $198 nationally.[54]

32. Missing one or more days from work not only means lost wages, but may also put the job itself at risk, leading to economic instability. In many cases, low-wage workers have unpredictable hours or are required as a condition of employment to regularly work overtime, both of which make it difficult to reliably plan appointments and related travel during non-work hours. It can be extremely difficult for low-wage workers to get a particular day off, particularly on short notice. And taking unapproved time off to keep an appointment or travel for abortion care can cost a patient her job.

33. Furthermore, some jobs that provide sick leave or paid leave may nonetheless require documentation of the reason for the leave. Women reluctant to disclose their abortions to their employers may therefore be unable to use paid or unpaid leave, even if their employer technically provides it; and those who do disclose their reason may have the request denied by a hostile employer or be vulnerable to retaliation as a result of their abortion.

Child Care

34. As noted, approximately 60% of women seeking an abortion have at least one child.[55] Consequently, traveling for an abortion, or making an unnecessary

[54] Rachel K. Jones et al., *At What Cost? Payment for Abortion Care by U.S. Women*, 23 Women's Health Issues e173, e174 (2013), https://www.ncbi.nlm.nih.gov/pubmed/23660430.

[55] *CDC Abortion Surveillance*, *supra* note 12, at Table 7.

or additional trip to a health care facility in order to obtain an abortion, may require child care arrangements, including when the abortion patient is the child's primary caregiver, or when the time needed for the appointment and travel to and from does not align with the child or children's regular childcare or school hours.

35. Child care costs can take up a significant proportion of a low-wage worker's income. In Hawai'i, costs range from $372 per month for part-time child care for a school-aged child to $589 per month for full-time infant care. Among the largest cities in the eight representative states analyzed above, full-time monthly child care for a preschooler ranges from $973 in Kansas City, MO (Jackson County), to $2,509 in Boston, MA. In rural counties across these states, a preschooler's full-time child care ranges in cost from $471 in Dallas County, MO, to $1,047 in Sandisfield, MA. Altogether, child care for just one preschooler ranges from 17% to 28% of the monthly needs budget across these eight states, averaging 21% of the budget.

36. But the daily rate for emergency short-term child care is often even greater than the daily rate for a month- or year-long slot. In addition, because many child care options, such as at a center or family home, are only available during regular daytime work hours, if a patient must be away overnight, the costs of child care are considerably higher. And if a woman cannot find or afford paid child care that aligns with her appointment and travel time, she may need to turn to a friend,

family member, or neighbor—which may require disclosing the reason she will be away, impinging on her privacy.

The Consequences of Attempting to Pay for Abortion-Related Travel

37. As detailed above, the total out-of-pocket costs involved in accessing abortion care can be substantial compared to income. For more than half of women attaining an abortion in a multi-state 2014 study, out-of-pocket costs (not including lost wages) averaged more than one-third of their personal monthly income.[56] In order to pay for these costs, low-income patients often end up making economic trade-offs that, as noted above, can carry serious consequences for their health, safety, and long-term economic stability.[57]

38. Indeed, a 2016 study concluded that two-thirds of women find it difficult or very difficult to pay for an abortion, and that doing so prevented or delayed nearly half of abortion patients from paying for at least one other basic need, including bills, food, rent, child care, and medical care.[58] Diverting funds from other basic needs in order to access an abortion can lead to additional costs and serious consequences. For instance, if a patient diverts any amount of rent funds and

[56] Roberts et al., *supra* note 6, at e211, e214.

[57] *Id.* at e216.

[58] Deborah Karasek & Sarah C.M. Roberts, *Abortion Patients' Experience and Perceptions of Waiting Periods: Survey Evidence before Arizona's Two-visit 24-hour Mandatory Waiting Period Law*, 26 Women's Health Issues 60, 63 (2016), https://www.whijournal.com/article/S1049-3867(15)00161-9/fulltext.

therefore cannot pay her full rent, she and her family risk eviction. Other consequences of having to divert funds include utility cut-offs, having to rely on food pantries or food banks, skipping meals, missing car payments, forgoing needed medical or dental care, or losing a scarce spot in a child care program.[59] Each of these in turn can lead to major long-term harms such as job loss, food insecurity, and medical harm.[60]

39. The most common source of money for an abortion is from the man involved in the pregnancy.[61] But borrowing from a partner can be problematic for some women, particularly where the relationship itself is unhealthy. The disclosure that results from the need for resources to cover travel and other costs (as well as

[59] Sandra S. Butler & Luisa S. Deprez, *The Parents as Scholars Program: A Maine Success Story*, 17 Me. Pol'y Rev. 40 (2008), http://digitalcommons.library.umaine.edu/mpr/vol17/iss1/7.

[60] Insurance does not change this calculus. Approximately two-thirds of the states restrict Medicaid coverage for abortion. Alina Salganicoff et al., *Coverage for Abortion Services and the ACA*, Kaiser Family Found. (Sept. 19, 2014), https://www.kff.org/womens-health-policy/issue-brief/coverage-for-abortion-services-and-the-aca/. Even in the states that do provide such coverage, many low-income women cannot access it because, for example, the income-eligibility threshold is too low, they are undocumented, or the time necessary to enroll will delay their abortion care beyond the time when they can access a medication abortion. *See* Kaiser Family Found., Health Care Coverage for Immigrants (2020), https://www.kff.org/racial-equity-and-health-policy/fact-sheet/health-coverage-of-immigrants/. A multi-state 2014 study found that nearly one-third of patients who appeared eligible for Medicaid coverage based on income and state of residency did not use Medicaid to pay for their abortions. Roberts et al., *supra* note 6, at e216. Many private or marketplace plans do not cover abortion either. Salganicoff et al., *supra*. Given this and other barriers, the same 2014 study found that only one in four patients with private insurance had their abortion covered by insurance. Roberts et al., *supra* note 6, at e216. And, the pandemic has increased the number of households that have lost health insurance coverage due to job loss and the associated loss of employer-provided health insurance. Furthermore, even for those who have coverage, Medicaid and private insurance do not cover other travel-related costs, such as meals, child care, and lost wages.

[61] Jones et al. (2013), *supra* note 54, at e177.

assistance with the travel itself) may increase the risk of domestic violence,[62] a widespread problem across the country.[63]

40. Other tactics to raise funds carry their own risks and consequences. Borrowing money from a payday lender or credit card company can help pay for an emergency expense, but repaying such loans may result in a cycle of refinancing, with additional fees and compounding interest leading to increasing debt.

41. Monetary costs alone do not fully capture how disruptive having to travel for abortion care can be. At each step, from arranging care for children, to informing supervisors or coworkers, to securing transportation and lodging, to obtaining resources (whether borrowed or diverted from other needs), the psychological harm increases and the circle of people aware of the reason for travel widens, breaching patient privacy, putting relationships or employment at risk, and increasing the risk of domestic violence.[64]

---

[62] Sarah CM Roberts, *Risk of Violence from The Man Involved In Pregnancy After Receiving or Being Denied An Abortion*, BMC Med. 12:144 (2014), at 1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4182793/.

[63] *See id.*; Ctrs. for Disease Control & Prevention, The National Intimate Partner and Sexual Violence Survey: 2015 Data Brief – Updated Release 2, 8 (2018) https://www.cdc.gov/violenceprevention/pdf/2015data-brief508.pdf (reporting that 43% of U.S. women had experienced some form of sexual violence in their lifetime, one in four experienced contact sexual violence, physical violence, or stalking by an intimate partner, and one in five experienced rape or attempted rape).

[64] Jill Barr-Walker et al., *Experience of Women Who Travel for Abortion: A Mixed Methods Systematic Review*, PLOS ONE 14(4), at 18 (2019), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0209991 ("Participants discussed how the need to secure time off of work, arrange childcare, or borrow money for travel

C. Research Confirms That Increased Travel to Obtain an Abortion Delays or Blocks Care

42. An extensive body of research supports the analysis above, documenting that the burdens and costs associated with traveling for abortion care delay or prevent patients from accessing care, decrease confidentiality, and increase the likelihood of anti-abortion stigma from employers, families, and/or friends.[65]

43. Research confirms that the greater the distance a patient must travel to access abortion, the less likely that the abortion will occur. For instance, a 2017 study evaluating the impact of a 2013 law that closed 24 of 41 abortion clinics in Texas—and thus increased the distance to the nearest clinic for many Texas women—found that the number of abortions declined 17% across the state between 2012 and 2014.[66] The magnitude of the decline in abortion rates increased more substantially as the distance from a patient's county of residence to the nearest abortion clinic increased: when the change in distance to an abortion clinic was 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%.[67]

---

or the procedure necessitated disclosing their decision to have an abortion to people at work and in their personal lives.").

[65] *Id.* at 2 (summarizing findings of multiple studies).

[66] 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.

[67] *Id.* at 438.

44. Other studies have documented this same inverse relationship between travel distance and abortion rates even for relatively short increases in distance. In Washington state, 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%.[68] 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.[69] And in Ohio, when clinics in Toledo and Lima closed, necessitating greater travel distances to reach an abortion provider, abortions rates in those counties and surrounding areas dropped by 25% or more the following year.[70]

45. The research literature also shows a complex interrelationship between travel costs, distance, and delay that in turn impacts access to abortion. Travel

[68] 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; *see also* 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).

[69] 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 (also finding a significantly greater increase in abortions in two counties distant from Atlanta after new abortion providers opened there, as compared to other counties in the state).

[70] Alison H. Norris et al., *Abortion Access in Ohio's Changing Legislative Context, 2010–2018*, 110 Am. J. Pub Health 1228, 1232 (2020) (abortion rate in rural counties disproportionately affected by clinic closures decreased more than 30% over study period).

burdens and costs can lead to delays in obtaining an abortion, which in turn can result in a patient being unable to access medication abortion or being turned away from the abortion clinic because by the time the patient is able to obtain the funds and make the necessary arrangements to get there, her pregnancy has advanced beyond the window for medication abortion care or the latest point in pregnancy at which the clinic provides services.[71] At the same time, delays can increase both the cost of the procedure (which typically increases as pregnancy advances and is greater for procedural abortion than medication abortion) and the cost of travel (for instance, if a patient must pay for lodging for a two-day procedure during the second trimester), thus causing further delay.[72] A nationwide 2014 study found that, for patients who were near a clinic's limit or were turned away because they exceeded that limit, the most cited reason for the delay was costs, for both travel and the procedure.[73] A 2010

[71] *See* Jerman et al., *supra* note 33, at 95, 98 (in qualitative study of 29 women traveling across state lines or long distances to access abortion in New Mexico and Michigan, most common consequence of travel and related barriers was "obtain[ing] abortions at later gestations than desired because of delays"); *see also* Norris et al., *supra* note 70, at 1233 (finding that patients in Ohio have abortions later in pregnancy than the national average and that this disparity increased as the number of facilities offering care in the state diminished).

[72] Jerman et al., *supra* note 33, at 100 (describing the "negative feedback loop," in which delay caused by difficulty raising money can lead to higher procedure costs and further delay); Diane Greene Foster & Katrina Kimport, *Who Seeks Abortions at or After 20 Weeks?*, 45 Persp. on Sexual & Reprod. Health 210, 214–15 (2013), https://doi.org/10.1363/4521013 (women who were 20 weeks or more pregnant reported difficulty getting to an abortion facility, spent more on travel, and experienced more delay); Norris et al., *supra* note 70, at 1233 (period of legislative and regulatory changes in Ohio that reduced access and resulted in clinic closures coincided with Ohioans being increasingly more likely to access abortion at later gestational ages).

[73] 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 and 67%

study in Illinois found that "[m]any women reported substantial difficulty locating a clinic, traveling long distances and finding transportation," and that such obstacles were associated with seeking abortion care in the second rather than the first trimester.[74]

III. CONCLUSION

46. At *least* three out of four abortion patients have income that is insufficient to meet their basic needs. The costs and burdens of traveling to obtain an abortion, arranging child care, and lost wages entirely prevent some women from obtaining abortion care. Even for those able to access care, these burdens force many patients to forgo other necessary expenses for themselves and their families and put them at risk of longer-term economic insecurity. In addition, these burdens force women to disclose their abortions to a wider circle of people than would otherwise be necessary, thus exposing some women and their families to domestic violence and/or longer-term economic insecurity.

arriving just before the limit attributed their delay to "travel and procedure costs," while 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, after "not recognizing pregnancy").

[74] Jessica W. Kiley et al., *Delays in Request for Pregnancy Termination: Comparison of Patients in the First and Second Trimesters*, 81 Contraception J. 446, 449 (2010), https://doi.org/10.1016/j.contraception.2009.12.021.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed in Friday Harbor, WA on April 12, 2021.

Diana M. Pearce

Diana M. Pearce, Ph.D.

Pearce Decl.

Appendix

APPENDIX: Comparison of Basic Needs Budgets in Eight States With Poverty Rates Close to National and Regional Averages

State Selection Methodology: To select states for this analysis, I used states that had poverty rates closest to the national and regional averages, according to U.S. Census Bureau data, and for which current Self-Sufficiency Standard data was available. State poverty rates and the national poverty rate refers to the latest two-year average (2018–19) provided by the Census Bureau.[1] To calculate regional averages, states were grouped by Census region: Northeast, Midwest, South, and West. The average regional percentage was then calculated using the state poverty rates for all states within that region. Finally, each state's percentage below-poverty was compared to the national average and the regional average, respectively, to determine the state or states closest to each average. If 2021 Self-Sufficiency Standard data was not available for the state with the closest rate to the national or regional average, the second-closest was used instead.

State Needs Budgets: For each state, I compared the Standard (*i.e.*, needs budget) for a family with one adult and one preschooler to the local or state minimum wage for (a) the county with the largest city; (b) the county with the median Standard in the state; and (c) the county with the lowest Standard in the state. The Standard was then compared to the minimum wage for each locality, assuming full-time work. Wherever possible, the cost of a given need in the Standard is based on the amount of financial assistance that the government (federal or state) has deemed minimally adequate for that basic need (such as housing, child care, or food expenses):

- Housing: maximum rent allowed for Section 8 voucher (housing assistance) recipients as set by the U.S. Department of Housing and Urban Development
- Child care: maximum amount set by the state for reimbursement for those receiving child care assistance (minus copayments)
- Food: the U.S. Department of Agriculture's "Low-Cost" Food Plan, which covers *only* the cost of basic groceries, without any take-out or restaurant food
- Transportation: cost of a monthly pass for local public transportation, or (if no adequate option) average cost of a private car, assuming use to/from work and one weekly shopping trip, based on national data such as U.S. Highway Administration's National Household Travel Survey, and U.S. Bureau of Labor Statistics' Consumer Expenditure Survey
- Health care: assuming employer-sponsored insurance and out-of-pocket costs based on the Medical Panel Survey, the most complete national source for health and insurance costs
- Miscellaneous: 10% of all other costs, and accounting only for essentials such as clothing, nonprescription medicines, and personal hygiene items, and not including any recreation, entertainment, savings, or debt repayment
- Taxes: federal and state income tax, payroll taxes, and state and local taxes (if applicable), and accounting for federal and applicable state tax credits

[1] *Income and Poverty in the United States*, U.S. Census Bureau, at Table: Percentage of People in Poverty by State Using 2- and 3-Year Averages: 2016–17 and 2018–19, https://www.census.gov/data/tables/2020/demo/income-poverty/p60-270.html (last visited Apr. 9, 2021).

National Average Poverty Rate (2018–19): 11.1%

Northeast
Average Poverty Rate (2018–19): 9.0%

	Closest to National Average			Closest to Regional Average		
	New York[2]			**Massachusetts[3]**		
	Largest city (Queens County)[4]	Median (Schoharie County)	Least expensive (Cattaraugus County)	Largest city (Boston)	Median (Phillipston)	Least expensive (Sandisfield)
Housing	$2,091	$938	$734	$2,509	$976	$1,175
Child care	$1,285	$840	$840	$1,502	$1,047	$1,047
Food	$471	$415	$371	$559	$470	$476
Transp'n	$127	$328	$315	$90	$308	$320
Health care	$535	$485	$451	$542	$534	$534
Misc.	$451	$301	$271	$520	$333	$355
Taxes	$1,469	$588	$434	$1,615	$789	$869
Earned Income Tax Credit	$0	$0	-$75	$0	$0	$0
Child Care Tax Credit	-$50	-$50	-$58	-$50	-$50	-$50
Child Tax Credit	-$167	-$167	-$167	-$167	-$167	-$167
Monthly Self-Sufficiency Standard	$6,212	$3,678	$3,116	$7,120	$4,240	$4,559
Minimum Wage	$15.00	$12.50	$12.50	$13.50	$13.50	$13.50
Ratio (Self-Suff. to Min. Wage)	**2.4**	**1.7**	**1.4**	**3.0**	**1.8**	**1.9**

[2] The Northeastern state closest to the national average was Maine (11.0%), but current Standard data for Maine is not available. The second-closest to the national average was New York (11.8%).

[3] The Northeastern state closest to the national average was Rhode Island (9.0%), but current Standard data for Rhode Island is not available. The second-closest to the regional average was Massachusetts (8.1%). Standard data in Massachusetts is grouped by town, not county, because towns are the more meaningful local geographic unit under Massachusetts's government structure.

[4] The largest city in New York (New York City) spans multiple counties; of those, Kings County is the most populous, but its Standard data is divided into two sub-regions to capture cost variations within the county. Queens County, the second-largest, has county-wide Standard data and is used instead for ease of comparison.

Midwest
Average Poverty Rate (2018–19): 9.7%

	Closest to National Average			losest to Regional Average		
	Missouri[5]			**Illinois[6]**		
	Largest city (Jackson County)	Median (Adair County)	Least expensive (Dallas County)	Largest city (Cook County)	Median (Jersey County)	Least expensive (Pike County)
Housing	$973	$662	$662	$1,197	$791	$700
Child care	$782	$486	$471	$1,179	$647	$547
Food	$388	$347	$378	$384	$380	$358
Transp'n	$352	$331	$337	$100	$275	$266
Health care	$603	$720	$646	$446	$594	$565
Misc.	$310	$255	$249	$331	$269	$244
Taxes	$739	$443	$418	$857	$600	$473
Earned Income Tax Credit	$0	-$95	-$110	$0	-$41	-$137
Child Care Tax Credit	-$50	-$60	-$63	-$50	-$55	-$63
Child Tax Credit	-$167	-$167	-$167	-$167	-$167	-$167
Monthly Self-Sufficiency Standard	$3,929	$2,922	$2,823	$4,277	$3,293	$2,787
Minimum Wage	$10.30	$10.30	$10.30	$13.00	$11.00	$11.00
Ratio (Self-Suff. to Min. Wage)	**2.2**	**1.6**	**1.6**	**1.9**	**1.7**	**1.5**

[5] Missouri's 2018–19 average poverty rate was 10.8%, the closest to the national average among Midwestern states.

[6] Illinois's 2018–19 average poverty rate was 9.8%, the closest to the regional average for Midwestern states.

South
Average Poverty Rate (2018–19): 13.2%

	Closest to National Average **Texas**[7]			Closest to Regional Average **North Carolina**[8]		
	Largest city (Harris County)	Median (Dallam County)	Least expensive (Uvalde County)	Largest city (Mecklenburg County)	Median (Jackson County)	Least expensive (Person County)
Housing	$1,129	$762	$734	$1,237	$718	$757
Child care	$788	$665	$509	$1,053	$688	$521
Food	$376	$374	$296	$435	$397	$375
Transp'n	$355	$311	$318	$301	$270	$276
Health care	$637	$683	$682	$495	$607	$454
Misc.	$329	$279	$254	$352	$268	$238
Taxes	$606	$458	$367	$880	$543	$405
Earned Income Tax Credit	$0	-$39	-$111	$0	-$47	-$136
Child Care Tax Credit	-$50	-$55	-$63	-$50	-$58	-$65
Child Tax Credit	-$167	-$167	-$167	-$167	-$167	-$161
Monthly Self-Sufficiency Standard	$4,004	$3,272	$2,820	$4,536	$3,219	$2,664
Minimum Wage	$7.25	$7.25	$7.25	$7.25	$7.25	$7.25
Ratio (Self-Suff. to Min. Wage)	**3.2**	**2.6**	**2.2**	**3.6**	**2.6**	**2.1**

[7] The Southern state closest to the national average was Oklahoma (12.1%), but current Standard data for Oklahoma is not available. The second-closest to the national average was Texas (12.4%).

[8] North Carolina's 2018–19 average poverty rate was 12.9%, the closest to the regional average for Southern states.

West
Average Poverty Rate (2018–19): 10.2%

	Closest to National Average **California**[9]			Closest to Regional Average **Arizona**[10]		
	Largest city (Los Angeles County)	Median (Riverside County)	Least expensive (Modoc County)	Largest city (Maricopa County)	Median (La Paz County)	Least expensive (Santa Cruz County)
Housing	$2,058	$1,417	$807	$1,259	$952	$788
Child care	$1,447	$1,054	$757	$879	$630	$700
Food	$448	$408	$435	$408	$396	$334
Transp'n	$342	$340	$323	$269	$241	$241
Health care	$507	$511	$849	$518	$624	$484
Misc.	$480	$373	$317	$333	$284	$255
Taxes	$1,145	$727	$571	$688	$524	$399
Earned Income Tax Credit	$0	$0	$0	$0	-$15	-$103
Child Care Tax Credit	-$50	-$50	-$50	-$50	-$53	-$63
Child Tax Credit	-$167	-$167	-$167	-$167	-$167	-$167
Monthly Self-Sufficiency Standard	$6,210	$4,613	$3,842	$4,138	$3,417	$2,868
Minimum Wage	$15.00	$14.00	$14.00	$12.15	$12.15	$12.15
Ratio (Self-Suff. to Min. Wage)	**2.4**	**1.9**	**1.6**	**2.0**	**1.6**	**1.4**

[9] California's 2018–19 average poverty rate was 11.0%, the closest to the national average among Western states.

[10] The Western state closest to the regional average was also California (11.0%). The second-closest was Arizona (11.4%).

Exhibit D

State of California
Office of the Attorney General
XAVIER BECERRA
ATTORNEY GENERAL

March 30, 2020

Secretary Alex M. Azar II
U.S. Department of Health & Human Services
200 Independence Ave., S.W.
Washington, DC 20201

Commissioner Stephen Hahn
U.S. Food & Drug Administration
10903 New Hampshire Ave., N.W.
Silver Spring, MD 20993

Dear Secretary Azar and Commissioner Hahn:

We write to request that you increase access to reproductive healthcare, including safe and legal abortion, during this pandemic. Specifically, as the U.S. Food & Drug Administration (FDA) considers policy changes in response to the Coronavirus Disease 2019 (COVID-19) public health emergency, we urge you to waive its Risk Evaluation and Mitigation Strategy (REMS), or use FDA enforcement discretion, to allow certified prescribers to use telehealth for Mifepristone, the medication abortion prescription drug.[1] The REMS create unnecessary delays for women who need access to time-sensitive healthcare and force them to travel unnecessarily.

During this unprecedented crisis, we need to ensure that women across the country have access to critical healthcare services. Steps have already been taken in many States at the behest of the federal government to increase telehealth. Yet, the current FDA REMS create unnecessary barriers between women and abortion care, not only making it harder to find—for example, by prohibiting sale by retail or mail-order pharmacies—but also making it unappealing to prescribe. By barring the use of telehealth, the REMS force women to travel at a time when many States and the federal government are urging people to stay home to curb the spread of COVID-19. Further, in some States across the country, like Texas and Ohio, politicians are using the pandemic to further restrict women's access to care by deeming abortion "nonessential" healthcare.[2] Denying women care and forcing them to travel unnecessarily is not

[1] FDA-2020-D-1106, https://www.regulations.gov/comment?D=FDA-2020-D-1106-0018.

[2] Sabrina Tavernise, *Texas and Ohio Include Abortion as Medical Procedures That Must Be Delayed*, New York Times (March 23, 2020), https://www.nytimes.com/2020/03/23/us/coronavirus-texas-ohio-abortion.html.

only shortsighted, it is putting women across the country in harm's way. Consequently, we urge you to act immediately and remove the FDA REMS designation.

Since 2000, Mifepristone has been approved by the FDA and remains the only drug approved in the United States for pregnancy termination. Since its approval, about three million women in the United States have used Mifepristone. And according to the FDA, this medication "has been increasingly used as its efficacy and safety have become well-established by both research and experience, and serious complications have proven rare."[3]

Despite Mifepristone's benefits and safety, the FDA subjects it to a REMS designation that is outdated, inconsistent with medical evidence, and limits healthcare providers' ability to use telehealth and provide this necessary drug, ultimately limiting patients' access to care. The Nation's leading reproductive healthcare specialists, the American College of Obstetricians and Gynecologists (ACOG), agree that the REMS are "outdated and substantially limit access to safe, effective medication," and have advocated for the FDA to remove the REMS.[4] Further, both the American Medical Association and American Academy of Family Physicians have also urged their removal.[5]

---

[3] Mifepristone is used in a regimen with the drug misoprostol as a medical option for terminating an early pregnancy. The FDA has approved the use of this regimen through 70 days (i.e. 10 weeks of pregnancy). The patient first takes Mifepristone, in a single oral dose on day one. Then, 24-48 hours later, she takes the misoprostol. Most women experience a miscarriage within 2 to 24 hours after taking the misoprostol. The FDA label does not specify where the patient should be located when she takes either medication; however, the REMS requirements dictate that she be handed the Mifepristone (but not the misoprostol) at a clinic, medical office, or hospital under the supervision of a health care provider.

[4] Improving Access to Mifepristone for Reproductive Health Indications, ACOG (June 2018) https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications.

[5] "The AAFP seeks changes in the drug's current REMS designation to conform to current evidence. This aligns with other medical specialty organizations, such as the American College of Obstetricians and Gynecologists. Recent research also indicates the agency's safety protocols are particularly stringent for the drug. Most importantly, the current drug label creates an unnecessary health care barrier for women who need it the most." Letter to the FDA, AAFP (June 20, 2019), https://www.aafp.org/dam/AAFP/documents/advocacy/prevention/women/LT-FDA-MifepristoneREMS-062019.pdf; *Mifepristone*, AMA Policy (2018), https://policysearch.ama-assn.org/policyfinder/detail/mifepristone?uri=%2FAMADoc%2FHOD.xml-H-100.948.xml

Under the REMS, the FDA requires that (1) a patient be handed the Mifepristone at a clinic, medical office, or hospital under the supervision of a healthcare provider; (2) the healthcare provider must be registered with the drug manufacturer; and, (3) the patient must sign a "Patient Agreement" form confirming that she has received counseling on the risks associated with Mifepristone. These onerous and medically unnecessary requirements limit healthcare providers' ability to assist their female patients, particularly during this global healthcare crisis.

For example, due to the REMS, patients have to travel to a designated clinic, medical office, or hospital, as opposed to getting a prescription from their doctor using telehealth, and then obtaining Mifepristone at a local pharmacy or delivered by mail. The FDA should not mandate this medically unnecessary travel, particularly during the COVID-19 crisis where not only are women being advised to stay home, but families are faced with additional childcare and financial constraints.

The REMS also require that a prescriber must be registered with the manufacturer in order to prescribe Mifepristone, which poses additional obstacles. Once a prescriber is certified, the prescriber must set up an account with the drug distribution company, provide the distribution company with a hard copy of their U.S. DEA license and state medical license, and then sign a special resolution to become a Mifepristone dispenser. These steps create delays and obstacles to accessing care for women under even the best of circumstances. In this time of crisis, when the States are being encouraged to expand use of telehealth in order to bend the curve and contain the spread of COVID-19, these REMS barriers on Mifepristone mean that providers cannot increase access to meet demand.

Yet, the most burdensome aspect of the REMS are the "Elements to Assure Safe Use." These requirements must be "commensurate with the specific serious risk[s]" listed in the drug label, "required as part of [a] strategy to mitigate" such risks, and not be "unduly burdensome on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas."[6] Mifepristone should not be subjected to these requirements when numerous medical studies have shown that Mifepristone is safe. In fact, Mifepristone is *four times* safer than Viagra and *fourteen times* safer than carrying a pregnancy to term. The FDA itself has stated that the "safety profile of Mifepristone is well-characterized and its risks well-understood after more than 15 years of marketing. Serious adverse events are rare and the safety profile of Mifepristone has not substantially changed." Furthermore, given the current pandemic, this requirement is imposing significant burdens on women in rural and medically underserved communities in accessing care, not to mention the additional burdens it imposes to all women across the country as the Centers for Disease Control and Prevention and the World Health Organization urge people to stay home.

---

[6] 21 U.S.C. §§ 355-1(f)(1)(A), 2(A), 2(C).

In light of the unprecedented COVID-19 crisis, we request you remove the FDA's restrictive REMS designation for Mifepristone thereby removing these unnecessary, undue burdens in accessing safe and time-sensitive, essential medical care. Alternatively, at a minimum, we request that you use your enforcement discretion to allow certified prescribers to use telehealth for mifepristone. As you know, all residents of California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Minnesota, New Mexico, New York, North Carolina, Oregon, and Vermont are ordered to shelter-in-place or are under similar restrictions, as are other Americans around the country, and our economy is feeling those immediate impacts. National public health experts urge the same nationwide. However, with the FDA's REMS designation, women seeking to obtain healthcare cannot abide by such requirements. These women are putting themselves and their families at risk when they seek out the healthcare that they need, and the federal government must act to ensure that no matter where they live, they can continue to receive necessary, safe, and legal abortion care.

Sincerely,

XAVIER BECERRA
California Attorney General

PHIL WEISER
Colorado Attorney General

WILLIAM TONG
Connecticut Attorney General

KATHLEEN JENNINGS
Delaware Attorney General

KARL A. RACINE
District of Columbia Attorney General

CLARE E. CONNORS
Hawai'i Attorney General

KWAME RAOUL
Illinois Attorney General

TOM MILLER
Iowa Attorney General

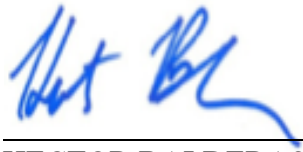
AARON M. FREY
Maine Attorney General

Brian E. Frosh
Maryland Attorney General

MAURA HEALEY
Massachusetts Attorney General

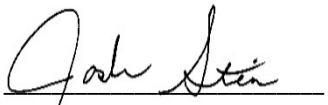
KEITH ELLISON
Minnesota Attorney General

AARON D. FORD
Nevada Attorney General



HECTOR BALDERAS
New Mexico Attorney General

LETITIA JAMES
New York Attorney General



JOSHUA H. STEIN
North Carolina Attorney General

ELLEN F. ROSENBLUM
Oregon Attorney General

JOSH SHAPIRO
Pennsylvania Attorney General

PETER F. NERONHA
Rhode Island Attorney General

Thomas J. Donovan, Jr.
Vermont Attorney General

Mark R. Herring
Virginia Attorney General

Exhibit E

Exhibit D

Nov. 3, 2015
Letter to FDA

CONFIDENTIAL

November 3, 2015

Robert M. Califf, MD, Deputy Commissioner for Medical Products and Tobacco
Janet Woodcock, MD, Director of the Center for Drug Evaluation and Research
Food and Drug Administration
10902 New Hampshire Avenue
Silver Spring, MD 20993

Dear Drs. Califf and Woodcock,

The US Food and Drug Administration approved mifepristone for use in medical abortions on September 28, 2000. Now, 15 years and over 2.5 million uses later, the safety and effectiveness of the drug have been well established by both research and experience, and serious complications have proven to be extremely rare.[1]

We the undersigned are researchers and providers of medical abortion. The organizations we represent include many of the practitioners of medical abortion in the United States. We are writing to present evidence demonstrating that some of the restrictions placed on mifepristone at its initial approval are no longer necessary for the safe and effective use of the drug. We encourage you to exercise your authority to change the label in order to improve both the use of the drug for medical abortion and access to it for this use.

We fully support the following changes to the label:

- The drug should be indicated for use in medical abortions beyond 49 days of gestation.
- The recommended dose regimen should be mifepristone 200 mg followed 24-48 hours later by misoprostol 800 mcg administered buccally.
- The location where the patient should take these drugs should not be restricted.
- An in-person visit should not be mandated for follow-up assessment.
- Any licensed healthcare provider – not just physicians – should be able to prescribe the drug.

All of these provisions are supported by overwhelming evidence and experience, and they reflect current practice in the United States. We hope and expect that you will agree.

We would like to focus here on two additional amendments to the current regulation of mifepristone:

A. Elimination or substantial modification of the Risk Evaluation and Mitigation Strategy (REMS), and
B. Extension of the gestational age limit for medical abortion to 70 days.

Below we discuss the rationale for each of these amendments. Because the elimination or modification of the REMS would have the greatest positive impact on the greatest number of women, we address it first.

A. Elimination or modification of the REMS

When the FDA first approved mifepristone in 2000, experience with its use in non-research settings was minimal, and the decision to impose specific conditions to minimize risk to users was therefore understandable. But over the past 15 years, the safety of the drug has been well established by both research and experience, and serious complications have proven to be extremely rare.[1] Thus, reassessment of the REMS and the Elements To Assure Safe Use (ETASU) which are included in the

FDA 1245

CONFIDENTIAL

current REMS is warranted. In our judgement, and based on scientific research and our collective experience, the ETASU are no longer justifiable.

As directed by Congress, the FDA may impose ETASU only when needed for the safe administration of the drug (Section 505-1 of the Federal Food, Drug, and Cosmetic Act). Under the law, the ETASU should be reassessed if they are unduly burdensome to the patient, such as when they impede access to health care by patients, including patients in rural or medically underserved areas (FDCA section 505-1(f)(2)(C)(II)). The ETASU requirements must be commensurate with the specific risks listed in the drug labeling, cannot be unduly burdensome on patient access to the drug, must conform with other components for other drugs with similar serious risks, and must be designed to be compatible with established distribution, procurement, and dispensing systems for drugs (FDCA section 355-1(f)(2)).

Below we review the specific components of the ETASU for mifepristone (Mifeprex) and provide our recommendations for modifying them.

1. Dispensing venues. The ETASU currently require that mifepristone must be dispensed to patients in a clinic, medical office, or hospital. This requirement meets none of the ETASU principles described above.

   - The requirement has no relation to the serious risks described in the "black box warning" on the mifepristone label which are "serious and sometimes fatal infections and bleeding". If these conditions occur, which the label notes happens "very rarely", they begin hours after the drug is ingested and thus cannot possibly be mitigated by requiring that the drug be dispensed in any specific venue. The same is true for all other adverse events listed on the mifepristone label. Notably, the ETASU does not specify that the drug must be ingested in the medical facility, only that it must be dispensed there. In fact, recent research has shown that allowing each patient to ingest the mifepristone in the place and time of her choosing is safe, desirable, and highly acceptable to women who choose the option.[2-4] This research further supports the conclusion that the location where the drug is dispensed has no bearing on risk.
   - The requirement creates a burden to access by necessitating that each providing facility must order supplies of the drug in advance of need, properly store these supplies, and maintain inventory records according to applicable pharmacy laws. These procedures are both financially and logistically onerous, particularly for small facilities. Anecdotal reports suggest that the burden is significant enough to dissuade some providers from offering the service to patients.
   - The requirement is not commensurate with the requirements for distribution of other drugs, including drugs that are much more immediately dangerous than mifepristone. For example, antibiotics, anti-hypertensives, erectile dysfunction drugs, and insulin have been reported to cause serious or fatal reactions shortly after use, yet are all distributed in pharmacies. Furthermore, since each medical abortion patient receives only a sufficient amount of mifepristone for her own abortion, risks such as overdose or redistribution that may be of concern for drugs that are dispensed in pharmacies in multiple doses are not salient for mifepristone. Moreover, mifepristone under the brand name Korlym is mailed by a specialty pharmacy directly to patients with Cushing's syndrome and is taken at home.

   Abortion providers certainly can safely evaluate patients and prescribe mifepristone without having the tablets physically present in their offices. We therefore recommend that this requirement be removed entirely and that mifepristone should be available in retail pharmacies like other prescription drugs.

CONFIDENTIAL

2. Provider certification. The ETASU require that to prescribe mifepristone, a provider must obtain certification by submitting a form attesting that he or she:
   - is able to assess the duration of pregnancy accurately;
   - is able to diagnose ectopic pregnancies;
   - is able to provide surgical intervention in cases of incomplete abortion or severe bleeding, or has made plans to provide such care through others, and is able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary; and
   - has read and understood the prescribing information.

   Fulfilling these criteria requires no specialized medical expertise. Although many clinicians use history and/or clinical examination to assess the duration and location of a pregnancy, any provider who is not comfortable with these approaches can order an ultrasound. Similarly, any provider can appropriately plan to provide care for emergencies by referring patients to an emergency room if needed. No licensed healthcare professional would be unable to read or understand the prescribing information. A standard clinical license should be sufficient to assure that a provider meets these qualifications; an exceptional certification for mifepristone is unnecessary.

   Provider certification for mifepristone is also inconsistent with the requirements for prescribing other drugs that require careful patient screening to ensure safety. For example, clinicians are not required to certify their ability to diagnose heart disease before prescribing powerful cardiovascular drugs, to diagnose infections before prescribing antibiotics, or to assess schizophrenia before prescribing antipsychotics. Evaluating a patient for each of these conditions is much more complicated than assessing the duration or location of a pregnancy. Singling out mifepristone for certification is inappropriate.

   Furthermore, the certification process inhibits access to mifepristone. Most immediately, because the certification process must be completed in advance of the patient encounter, it prevents qualified clinicians who have not completed the certification from providing the service to patients who present for care unexpectedly. More broadly, the process of obtaining certification may discourage some providers from offering the service to any patients. Given the history of harassment and violence against abortion providers in this country and the demonstrated difficulty in maintaining confidentiality in the current environment, some clinicians are understandably reluctant to allow their names to be included in a list of abortion providers.

   Finally, the certification requirement should be eliminated because it would be incompatible with standard distribution of mifepristone in pharmacies. Setting up and maintaining a system whereby pharmacies could check the certification status of prescribers would be impractical.

3. Patient Agreement. The requirement that each patient should sign an FDA-approved agreement before receiving mifepristone should also be eliminated. Like the other parts of the ETASU, this requirement is inconsistent with requirements for other drugs with similar or greater risks. Medical abortion is a treatment, not a procedure, and it is highly unusual to require patients to sign agreements for other safe treatments – for example, treatment of a sexually transmitted infection, or a nebulizer treatment for asthma. In addition, in places where off-label use of mifepristone is permitted, the content of any FDA-approved agreement may be inconsistent with the care provided by the individual clinician. The requirement that a patient sign an agreement to a treatment plan that differs from the one offered by her provider is both inappropriate and confusing.

CONFIDENTIAL

Making these changes to the ETASU would render other parts of the REMS obsolete. For example, the distributor certification, as currently written, would become unnecessary if provider certification were not required and pharmacy distribution were permitted. If the ETASU elements are eliminated, the REMS Assessments are no longer needed either. We recommend that the REMS should be discontinued in its entirety, consistent with the FDA's current efforts to decrease disruption to the healthcare system caused when some drugs are subject to distribution requirements that differ from the norm.

The immense volume of data about and experience with mifepristone since its initial approval have demonstrated that this drug is extremely safe and can be appropriately provided by clinicians with routine professional training. Standard professional labeling is clearly sufficient to ensure that its benefits outweigh its risks.

B. Extension of the gestational age limit to 70 days

Substantial evidence demonstrates that the proposed medical abortion regimen is highly effective in the 10th week (64-70 days) of gestation (defined as days since onset of the last menstrual period or estimated days since ovulation + 14). A recent systematic review identified four published prospective studies that recorded data on outcomes of medical abortions performed during this 10th week.[5] We have subsequently found two additional published studies,[6,7] and Gynuity Health Projects recently has conducted two additional studies that are not yet published that also include such data. The published studies were conducted in the United States,[8] Mexico,[9,10] Curaçao,[11] Vietnam,[6,7] and the Republic of Georgia,[7] and the two unpublished studies were conducted in the United States and Mexico. All subjects were treated as outpatients between 2007 and 2015.

The eight studies included a combined total of 634 women treated at 64-70 days of gestation, of whom 587 (91%) provided outcome data (Table 1). Of these women, 92.4% (95% CI 89.9%, 94.4%) had complete medical abortion success (pregnancy termination without resort to surgical intervention), and 3.1% (95% CI 1.9%, 4.9%) had ongoing pregnancies (Table 1). These proportions were not clinically or statistically different from the results obtained in women treated in the 9th gestational week (57-63 days) in the same studies (Table 2). Perhaps more importantly, the complete abortion success rate was comparable to the standard set by the FDA for medical abortion effectiveness in its initial approval of mifepristone in 2000; the proportion of subjects with complete abortion success in the US pivotal trial that supported that approval was 92.1%.[12]

Data from the eight studies also document that medical abortion in the 10th gestational week is safe. Only 7 of the 578 subjects (1.2%, 95%CI 0.5%, 2.5%) treated in that week had serious adverse events, a proportion nearly identical to that among subjects treated in the 9th gestational week (11/1010, 1.1%, 95%CI 0.5%, 1.9%). Two of the studies found that women treated at 64-70 days experienced more side effects, such as vomiting, diarrhea, and weakness, than women treated in the prior week, but these events were managed on an outpatient basis and were self-limited.[8,9] The same two studies also reported data on satisfaction; in these studies, more than 75% of the women treated in the 10th week noted that their medical abortion was satisfactory or would choose it over surgical abortion for a future abortion.

Based on these published and well-known data, medical abortion practice in the United States is rapidly expanding to include provision of the service through 70 days of gestation. The National Abortion Federation updated its Clinical Practice Guidelines in 2013 to recommend the 70-day gestational age limit, and in 2015, 55% of respondents to the annual NAF member survey reported providing medical abortion up to 70 days (Vicki Saporta, President, NAF, personal communication June 10, 2015). Similarly,

CONFIDENTIAL

over the past several years, about half of Planned Parenthood affiliates have indicated their intentions to offer services to women up to 70 days, and have provided services to hundreds of women at 64-70 days of gestation (Deborah VanDerhei, National Director, CAPS, Planned Parenthood Federation of America, personal communication June 10, 2015).

Considering the current evidence, we submit that medical abortion is safe and effective through at least 70 days since last menstrual period (LMP) and that a label specifying a maximum gestational age less than that is unnecessarily and arbitrarily conservative. Women who present for abortion in the 10th gestational week currently constitute about 7% of all abortion patients nationally.[13] This is a significant proportion and limitations to access to medical abortion would have significant negative consequences for those women.

Although off-label use of drugs is generally accepted in the United States, many clinicians see FDA labels as guides to appropriate and legally defensible clinical practice. A gestational limit lower than 70 days on the mifepristone label may discourage some clinicians from offering medical abortion to this subgroup of patients. In addition, in states where off-label use of mifepristone is prohibited by law, women at a later gestational age would be entirely prevented from accessing medical abortion. Because of these state laws demanding strict compliance with the label, it is important for the FDA to include on the label all situations where medical abortion is safe and effective. And as a growing number of non-hospital abortion providers offer medical abortion but not surgical abortion,[14,15] these women will need to travel farther and at greater cost to access abortion services at all.

The data presented here are sufficient to establish the efficacy and safety of outpatient medical abortion with mifepristone and misoprostol through 70 days LMP. Including this information on the mifepristone label would be consistent with the FDA's mission to promote public health through the effective and safe use of drugs. Furthermore additional studies of outpatient medical abortion through 70 days LMP are ongoing and we would be happy to forward more information as it becomes available.

We would be happy to provide further details regarding the data we have presented. We appreciate your consideration of the requests that we have made in this letter.

Respectfully yours,

Kelly Blanchard, MSc
President, Ibis Reproductive Health

Paul Blumenthal, MD, MPH
Professor, Department of Obstetrics and Gynecology
Director, Stanford Gynecology Service
Director, Stanford Division of Family Planning Services and Research
Stanford University School of Medicine

Eve Espey, MD, MPH
Professor and Chair, Department of Obstetrics and Gynecology
Director, Family Planning Fellowship
University of New Mexico School of Medicine

Signatures continue on following page

CONFIDENTIAL

Angel M. Foster, DPhil, MD, AM
Chair of the Population, Reproductive, and Sexual Health Section
American Public Health Association
Endowed Chair of Women's Health Research
Institute of Population Health
University of Ottawa

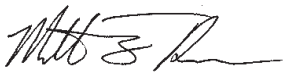
Marji Gold, MD
Professor, Family and Social Medicine
Director, Family Planning Fellowship
Director, Center for Reproductive Health Education in Family Medicine
Albert Einstein College of Medicine/Montefiore Medical Center

David A. Grimes, MD
Clinical Professor, Department of Obstetrics and Gynecology
University of North Carolina School of Medicine

Daniel Grossman, MD
Director, Advancing New Standards in Reproductive Health
Professor, Department of Obstetrics, Gynecology and Reproductive Sciences
University of California San Francisco
Senior Advisor, Ibis Reproductive Health

Elizabeth Raymond, MD, MPH
Senior Medical Associate, Gynuity Health Projects

Matthew Reeves, MD, MPH
Medical Director, National Abortion Federation



James Trussell, PhD, B.Phil
Professor of Economics and Public Affairs, Emeritus
Senior Research Demographer, Office of Population Research
Princeton University

Carolyn Westhoff MD, MSc
Sarah Billinghurst Solomon Professor of Reproductive Health
Columbia University Medical Center

Beverly Winikoff, MD, MPH
President, Gynuity Health Projects
Professor, Clinical Population and Family Health
Mailman School of Public Health, Columbia University

Signatures continue on following page

CONFIDENTIAL

Organizational Signatories

American Public Health Association, Population, Reproductive, and Sexual Health Section

National Abortion Federation

Ibis Reproductive Health

Gynuity Health Projects

Exhibit F

Exhibit E

Nov. 4, 2015
Letter to FDA

ACOG
THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

Executive Vice President & Chief Executive Officer
Hal C. Lawrence, III, MD, FACOG
Office: (202) 863-2500
Facsimile: (202) 863-1643

November 4, 2015

Robert M. Califf, MD, Deputy Commissioner for Medical Products and Tobacco
Janet Woodcock, MD, Director of the Center for Drug Evaluation and Research
Food and Drug Administration
10902 New Hampshire Avenue
Silver Spring, MD 20993

Dear Drs. Califf and Woodcock:

On behalf of the American Congress of Obstetricians and Gynecologists (ACOG), an organization representing 58,000 physicians and partners in women's health, I would like to present our recommendations regarding the safety, effectiveness, and use of mifepristone. We hope this information will be useful to FDA in any future deliberations regarding revisions to the drug label, Risk Evaluation and Mitigation Strategy (REMS), and Elements To Assure Safe Use (ETASU).

Since FDA approval in 2000, mifepristone has been used by women over 2.5 million times as a safe, effective method of pregnancy termination. As outlined in the enclosed Committee Opinion #613, ACOG supports access to safe, legal abortion services as a necessary component of women's health care, supports the availability of high-quality reproductive health services for all women, and is committed to improving access to abortion. As our knowledge regarding mifepristone advances, we believe its labeling, REMS, and ETASU have become outdated and have limited women's access to safe, effective abortion care.

ACOG supports evidence-based regimens for provision of medication abortion services, as outlined in the enclosed Practice Bulletin #143. These evidence-based regimens have improved medication abortion in terms of expense, safety, speed, and adverse effects. Based on efficacy and the adverse effect profile, evidence-based protocols for medication abortion are superior to the FDA-approved regimen.

Regimens that use low doses of mifepristone (200 mg) have similar efficacy and lower costs compared with those that use mifepristone at 600 mg. Vaginal, buccal, and sublingual routes of misoprostol administration increase efficacy, decrease continuing pregnancy rates, and increase the gestational age range for use as compared with the FDA-approved regimen. ACOG supports efforts to align FDA labeling for mifepristone with evidence-based regimens.

In addition, ACOG would fully support the following changes to the current label, consistent with ACOG recommendations outlined in Practice Bulletin #143:

1. The drug should be indicated for use in medical abortions up to 70 days of gestation

   Although the method is most commonly used up to 63 days of gestation, the treatment is also effective after 63 days gestation[i].

2. The location where the patient should take these drugs should not be restricted

   There is no clinical justification for restrictions or regulations regarding the location of mifepristone or misoprostol ingestion or administration.

3. An in-person visit should not be mandated for follow-up assessment

   Follow-up after medication abortion is important, although an in-clinic evaluation is not always necessary.

4. Any licensed healthcare provider should be able to prescribe the drug, not just physicians

   Medication abortion can be provided safely and effectively by nonphysician clinicians.

In addition to the above recommendations, ACOG finds evidence regarding the safety of the drug over the past 15 years of use in the United States to be a compelling argument for the removal or substantial modification of the Risk Evaluation and Mitigation Strategy (REMS) and Elements to Assure Safe Use (ETASU) for mifepristone[ii]. These requirements are inconsistent with requirements for other drugs with similar or greater risks and serve as barriers to access without demonstrated improvements to patient safety or outcomes. Prescription access to medication abortion has been shown to improve access to care, and could also facilitate expansion of telemedicine models of provision that have been shown to increase access, particularly for women in rural areas.[iii] [iv] [v]

ACOG opposes regulations or restrictions that are inappropriately unique to the provision of abortion and that mandate procedures and care that are not evidence-based. The safety record of this drug does not warrant restrictions such as provider certification, dispensing of the drug in specific locations, or specified patient consent. A standard clinical license should be sufficient to ensure that a practitioner meets qualifications for prescribing mifepristone. Mandating the location where the drug is to be dispensed has no bearing on risk. The requirement that patients sign an FDA-approved agreement before receiving mifepristone is inconsistent with requirements for other drugs with similar or greater risks. In line with its safety record and to improve access, we recommend that mifepristone be made available in retail pharmacies like other prescription drugs, without unique provider certification or patient consent requirements.

Thank you for your consideration. We are available to answer any questions you may have regarding these issues.

Sincerely,

Hal C Lawrence MD

Hal C. Lawrence, III, MD, FACOG
Executive Vice President and CEO

[i] Abbas D, Chong E, Raymond EG. Outpatient medical abortion is safe and effective through 70 days gestation. Contraception 2015;92:197-9.
[ii] Cleland K, Smith N. Aligning mifepristone regulation with evidence: driving policy change using 15 years of excellent safety data. Contraception 2015;92:179-181.
[iii] Grossman D, Goldstone P. Mifepristone by prescription: a dream in the United States but reality in Australia. Contraception 2015; 92:186–189.
[iv] Grossman D, Grindlay K, Buchacker T, Lane K, Blanchard K. Effectiveness and acceptability of medical abortion provided through telemedicine. Obstet Gynecol 2011; 118:296–303.
[v] Grossman DA, Grindlay K, Buchacker T, Potter JE, Schmertmann CP. Changes in service delivery patterns after introduction of telemedicine provision of medical abortion in Iowa. Am J Public Health 2013; 103:73–8.

Exhibit G

Remarks by Secretary Xavier Becerra at the Press Conference in Response to President Biden's Directive following Overturning of Roe v. Wade

Xavier Becerra
June 28, 2022
Hubert H. Humphrey Building
Washington, D.C.

As Prepared for Delivery

On Friday, June 24th, five Americans decided to use the vast power bestowed upon them by our democracy and our Constitution to unconscionably put at risk the life and health of millions of their fellow Americans. They chose to unconscionably limit Americans' established freedom and autonomy to control their own body — decisions usually made in consultation with their doctor, not a politician. And they chose to unconscionably strip away the fundamental health care protections that every American of child-bearing age has known all their lives.

Friday's Supreme Court decision was despicable, but it was also predictable. HHS has been preparing for this for some time. That's why, earlier this year, we launched our HHS Reproductive Access Task Force to plan for every action necessary to protect women's access to reproductive health care.

There is no magic bullet. But if there is something we can do, we will find it and we will do it at HHS. Indeed, that was the instruction I received from the President of the United States.

Last Friday, President Biden announced the actions he is taking to ensure medication abortion is available to the fullest extent possible and that women can travel safely from states where abortion is banned to states where abortion is legal. Here is how HHS will support these issues:

- First, HHS will take steps to increase access to medication abortion.

  - Federal law requires our programs to provide medication abortion in limited circumstances, including life of the woman, rape, or incest.

- Now more than ever it is imperative that all federally-supported programs and services are complying and providing this under the law.

- Second, I am directing the Office for Civil Rights within HHS to ensure patient privacy and nondiscrimination for patients seeking reproductive health care, as well as for providers who offer reproductive health care.

- Third, I am directing the Department to examine its authority under the Emergency Medical Treatment Act (EMTALA) to ensure that clinical judgment of doctors and hospitals is supported in treating pregnant patients, including those experiencing pregnancy loss or complications, and reaffirming that abortion care can be appropriate to stabilize patients.

- Fourth, I am directing all agencies in my Department to work to ensure that all providers – from doctors to pharmacists -- and clinics have appropriate training and resources to handle family planning needs, including administering patient referrals for care, and helping patients navigate this new reality.

- Fifth, I am directing the Centers for Medicare and Medicaid Services (CMS) to take every legally available step to protect family planning care, including emergency contraceptives and long acting reversable contraceptives, such as IUDs. Health care is a matter to be decided by patients and their providers, not politicians. As part of these efforts, we will make clear that family planning providers are able to participate in the Medicaid program. These clinics provide safe care and have a vast expertise in providing reproductive health care.

Let me now tell you a little more about why I think medication abortion is so critical.

- Medication abortion has been approved by the FDA for years and is safe for patients.

- It is the gold standard for care when someone who's pregnant experiences a miscarriage, which is all too real for many expectant mothers across the country.

- The Supreme Court's decision will result in worsened health outcomes and death for some patients. Working to increase access to this drug is a national imperative and in the public interest.

- We will continue to support the FDA and its rigorous scientific review for these safe and effective drugs.

- We will also work with the Attorney General and the Justice Department as they work to ensure that states may not ban medication abortion, based on a disagreement with the FDA's expert judgment about the drug's safety and efficacy.

- And we will issue guidance to providers to ensure they receive accurate and robust information on medication abortion.

The HHS Reproductive Access Task Force will report to me on additional impactful ways to ensure appropriate information about, access to, and coverage for sexual and reproductive health care – as well as coordinate with other federal agencies.

I was at a Planned Parenthood clinic in St. Louis, Missouri, on Friday morning when the Supreme Court overturned Roe v. Wade. I saw in real time the impact of this unconscionable decision. The Clinic Director had to almost immediately start turning away patients as the state's ban went into effect. This clinic has stopped providing safe and legal abortion care. People in the room were visibly shaken, there were tears and an unshakeable sense of sadness.

After my visit to the clinic in St. Louis, I traveled across the state line to another clinic in Fairview Heights, Illinois – a state that, unlike Missouri, still had lawful abortion care. There, I visited a site that helps patients get care by providing assistance – ranging from helping patients find appointments to paying for their travel expenses –and abortion care. It was shocking that, in the United States of America, a short drive can make such a dire and draconian difference in health care outcomes. I saw restrictions that leave women and families on unequal footing and widen maternal health disparities.

The impact was visible and real.

This is a critical moment in history. How we respond will speak to how we view the rights, dignity and wellbeing of women everywhere. This is a moment of crisis in health care. We will leave no stone unturned. All options are on the table. We will do everything within the legal limit of the law to reach patients and support providers.

I know we are all tired and our hearts are broken by this loss of rights and dignity. But now is the time for us to continue on for the many people across the country who live in banned abortion states, who lack voices that represent them.

I stand with you and I have your back.

HHS Headquarters

U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Toll Free Call Center: 1-877-696-6775

Exhibit H

AAFP
AMERICAN ACADEMY OF FAMILY PHYSICIANS

June 20, 2019

Norman Sharpless, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue NW
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless:

On behalf of the American Academy of Family Physicians (AAFP), which represents 134,600 family physicians and medical students across the country, I write to convey the organization's support for removing the current Risk Evaluation and Mitigation Strategy (REMS) and Element to Assure Safe Use (ETASU) status for mifepristone, the drug regime that can medically induce abortion and help provide miscarriage treatment.

The AAFP seeks changes in the drug's current REMS designation to conform to current evidence. This aligns with other medical specialty organizations, such as the American College of Obstetricians and Gynecologists. Recent research also indicates the agency's safety protocols are particularly stringent for the drug. Most importantly, the current drug label creates an unnecessary health care barrier for women who need it the most.

Section 501-1 of the *Food, Drugs, and Cosmetics Act* (21 U.S.C. 355-1) indicates that the agency must evaluate if a drug's risks outweigh benefits. Since mifepristone entered the market in 2000, nearly 3 million women have used it, along with misoprostol, for essential medical care with a high degree of effectiveness (over 97%) and minor complication risks (less than 1%), particularly when accessing it early. In addition, the drug regime poses far fewer risks than medications with similar safety standards in place such as Accutane, which is associated with risk for birth defects. For women, particularly those in rural and medically-underserved areas who typically lack health care options, current protocols may result in delays that may increase their need for surgical abortion. This also applies for those who may need miscarriage treatment where efficient mifepristone usage may be the most patient-centered option.

Again, we urge your consideration of this request. For more information, please contact Sonya Clay, Government Relations Representative, at 202-232-9033 or sclay@aafp.org.

Sincerely,

Michael L. Munger, MD, FAAFP
Board Chair

1133 CONNECTICUT AVE., N.W., STE. 1100 | WASHINGTON, DC 20036-4305 | (800) 794-7481 | (202) 232-9033

Exhibit I

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, on behalf of its members and members' patients; COUNCIL OF UNIVERSITY CHAIRS OF OBSTETRICS AND GYNECOLOGY, on behalf of its members and members' patients; NEW YORK STATE ACADEMY OF FAMILY PHYSICIANS, on behalf of its members and members' patients; SISTERSONG WOMEN OF COLOR REPRODUCTIVE JUSTICE COLLECTIVE, on behalf of its members and members' patients; and HONOR MACNAUGHTON, M.D.,

Plaintiffs,

vs.

UNITED STATES FOOD AND DRUG ADMINISTRATION; STEPHEN M. HAHN, M.D., in his official capacity as COMMISSIONER OF FOOD AND DRUGS, and his employees, agents and successors in office; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and ALEX AZAR, J.D., in his official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and his employees, agents and successors in office;

Defendants.

CIV. NO.

[CIVIL RIGHTS ACTION]

COMPLAINT

INTRODUCTION

1. COVID-19, the disease caused by novel coronavirus SARS-CoV-2, has swept the globe in a pandemic that has upended normal life. In the four months since the first U.S. case was reported, more than 1.5 million people have been infected and 100,000 people have died in the United States alone. The pandemic has been particularly devastating in low-income communities and communities of color, where it is disproportionately severe and fatal.

2. Because the virus is highly contagious and can be transmitted by people who are asymptomatic, and because there is no vaccine, the principal way to slow transmission and reduce the death rate is by limiting physical interactions.

3. To protect both patients and clinicians, there has been a massive, nationwide effort to meet patients' medical needs without unnecessary travel and in-person interactions that facilitate viral spread. In particular, clinicians in virtually every area of health care are relying on telemedicine: the use of technology to connect patients with clinicians who are not in the same physical location.

4. The U.S. Centers for Disease Control and Prevention ("CDC") within Defendant U.S. Department of Health and Human Services ("HHS") have issued guidance to health care professionals that "[l]everaging telemedicine whenever possible is the best way to protect patients and staff from COVID-19." Accordingly, Defendants HHS and U.S. Food and Drug Administration ("FDA") have taken substantial action both to encourage telemedicine use and to give clinicians the flexibility—even for highly regulated drugs—to allow their patients to forgo unnecessary in-person visits where appropriate in the clinician's medical judgment.

5. But there is a striking exception. Defendants continue to subject mifepristone (brand name Mifeprex®), one of two FDA-approved prescription drugs used in combination to

end an early pregnancy or to manage a miscarriage, to a Risk Evaluation and Mitigation Strategy ("REMS") that mandates unnecessary travel and personal interactions, jeopardizing the health and lives of patients and clinicians.

6. Specifically, Defendants require patients to travel to their clinician's hospital, clinic, or medical office to pick up the pill ("Mifepristone In-Person Dispensing Requirement" or "Requirement"). Patients who have already been evaluated by a clinician through telemedicine or at a prior in-person visit are not allowed to fill their mifepristone prescription by mail: they still must travel to one of these clinical settings to pick up the pill, even if they will be receiving no in-person medical services at that time.

7. Defendants require patients to obtain mifepristone only in these clinical settings even though the FDA permits patients to swallow the pill later at home without clinical supervision. Of the more than 20,000 drugs regulated by the FDA, mifepristone is the *only* one that patients must receive in person at a hospital, clinic, or medical office, yet may self-administer, unsupervised, at a location of their choosing.

8. Moreover, when not used for abortion or miscarriage, the FDA authorizes mailing the identical chemical compound to patients' homes in higher doses and much larger quantities.

9. If not for this restriction, patients seeking abortion or miscarriage care who have obtained a prescription for mifepristone based on a telemedicine consultation or prior in-person visit could obtain the medication safely by mail without facing needless SARS-CoV-2 exposure. The CDC, a component agency of Defendant HHS, has specifically advised patients to obtain medications via telehealth and mail-order delivery wherever possible to mitigate exposure risks.

10. In response to the public health emergency, Defendants have waived enforcement of other REMS requirements necessitating in-person visits, such as those requiring laboratory

testing or magnetic resonance imaging ("MRIs") before prescription, and partnered with other federal agencies to suspend rules requiring in-person visits before prescribing controlled substances. Leading medical and public health experts, including Plaintiffs American College of Obstetricians and Gynecologists and New York State Academy of Family Physicians, have petitioned the FDA to similarly lift the Mifepristone In-Person Dispensing Requirement during the pandemic, and thereby afford mifepristone prescribers the flexibility to forgo medically unnecessary in-person visits, consistent with their best clinical judgment, during this crisis.

11. Despite this national medical consensus, Defendants have maintained the Requirement during the pandemic, forcing patients to put themselves at increased risk of contracting COVID-19 as a condition of obtaining abortion or miscarriage care and needlessly raising exposure risks for clinicians and other health care staff.

12. Because of this medically unnecessary requirement, patients seeking abortion or miscarriage care during the pandemic must bear the infection risks associated with travel, childcare, and physical interactions at a hospital, clinic, or medical office.

13. For the majority of abortion patients who are low-income, paying for an abortion and arranging transportation and childcare to obtain care is already very difficult. The need to raise funds for and arrange such travel and logistics has long been shown to delay access to time-sensitive abortion care even under normal circumstances. During a historic unemployment crisis, when many schools and daycares are closed because of the life-threatening risks associated with physical interactions, such patients are even more likely to suffer delays that will push some to the point in pregnancy when medication abortion is no longer available and an in-office procedural abortion is the only option. This, too, unnecessarily increases medical risks: the more time spent inside a health care facility and the more individuals with whom a patient interacts, the greater the

risk of SARS-CoV-2 exposure.

14. Similarly, the Requirement forces some patients suffering a miscarriage to choose between subjecting themselves to a heightened risk of COVID-19 in order to obtain mifepristone, or using an inferior treatment regimen that is less likely to effectively complete the miscarriage, necessitating a subsequent in-office procedure that, in turn, raises exposure risks.

15. By making life-threatening viral exposure risks a condition of treatment for medication abortion and miscarriage care, the FDA's continued maintenance of the Mifepristone In-Person Dispensing Requirement jeopardizes the safety of patients, clinicians, and the public at large, with no countervailing benefit—and with particularly severe implications for low-income people and people of color, who comprise a disproportionate share of impacted patients and who are already suffering and dying from COVID-19 at substantially higher rates.

SUBJECT MATTER JURISDICTION & VENUE

16. The Court has subject matter jurisdiction over Plaintiffs' claims under Article III of the Constitution, 28 U.S.C. § 1331, and 28 U.S.C. § 1346. An actual and justiciable controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other relief pursuant to 28 U.S.C. §§ 2201-2202 and the Court's inherent equitable powers. Plaintiffs have no adequate remedy at law.

17. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e)(1) because this is a judicial district in which Defendants FDA and Commissioner Hahn reside and this action seeks relief against federal agencies and officials acting in their official capacities; and because a substantial part of the events and omissions giving rise to this action occurred in this district.

PARTIES

Plaintiffs

18. Plaintiff the **American College of Obstetricians and Gynecologists** ("ACOG") is the nation's premier professional membership organization for obstetrician-gynecologists, representing more than 60,000 members across every state, who in turn treat tens of millions of patients across the United States. ACOG is headquartered at 409 12th Street SW, Washington, D.C. 20024-2188.

19. ACOG supports its members in numerous ways, including producing practice guidelines, providing practice management and career support, facilitating programs and initiatives aimed at improving women's health, and advocating on behalf of members and patients on matters pertaining to the provision of reproductive health care. ACOG Fellows are board-certified obstetrician-gynecologists whose professional activities are devoted to the practice of obstetrics and/or gynecology, who possess unrestricted licenses to practice medicine, and who have attained high ethical and professional standing. ACOG members also include physicians in other specialties and allied health professionals who meet certain educational and professional criteria and can contribute to ACOG's mission and programming. ACOG's members include physicians and other clinicians who are certified under the mifepristone REMS and who prescribe mifepristone for abortion and miscarriage care.

20. As described *infra*, the Mifepristone In-Person Dispensing Requirement impedes ACOG's members' ability to reduce risks of exposure to SARS-CoV-2 for themselves, their staff, and their patients in accordance with their professional judgment, and imposes unnecessary medical risks and other harms on ACOG's members and their patients during the COVID-19 pandemic. ACOG sues on behalf of its members and its members' patients.

21. For instance, ACOG member Angela Chen, M.D., M.P.H., FACOG, is a certified mifepristone prescriber under the REMS who prescribes mifepristone for both abortion and miscarriage care to her patients at a faculty practice affiliated with the department of obstetrics and gynecology at the University of California, Los Angeles, Medical Center, and at an outpatient clinic where she supervises and trains residents. Because of the Mifepristone In-Person Dispensing Requirement, some of Dr. Chen's patients seeking abortion and miscarriage care must travel unnecessarily to her health care facility to obtain the mifepristone pill, even when they will be receiving no in-person medical services at that time. The Requirement subjects Dr. Chen and her patients to needless viral exposure risks and other harms, and impedes her from exercising her clinical judgment during the COVID-19 pandemic. If not for the Requirement, some of Dr. Chen's patients could and would obtain mifepristone by mail, without having to make a medically unnecessary trip to her health care facility.

22. Plaintiff the **Council of University Chairs of Obstetrics and Gynecology** ("CUCOG") is a nationwide membership association promoting excellence in medical education in the fields of obstetrics and gynecology. CUCOG has 146 members representing the departments of obstetrics and gynecology within or affiliated with schools of medicine in 48 states, the District of Columbia, Puerto Rico, and Canada, with the department chair as the acting liaison. CUCOG convenes university chairs of obstetrics and gynecology in order to support the major missions of academic medicine: the provision of high-quality, safe, effective, and compassionate clinical care, including reproductive health care, in academic settings; the provision of high-quality medical education; and the cultivation of useful, reliable research. In addition, CUCOG provides a leadership learning community for chairs and aspiring chairs. CUCOG's members include physicians who are certified under the mifepristone REMS and who prescribe mifepristone for

abortion and miscarriage care. CUCOG is headquartered at 230 W. Monroe, Suite 710, Chicago, Illinois 60606.

23. As described *infra*, the Mifepristone In-Person Dispensing Requirement impedes CUCOG's members' ability to reduce risks of exposure to SARS-CoV-2 for themselves, their staff, and their patients in accordance with their professional judgment, and imposes unnecessary medical risks and other harms on CUCOG's members and their patients during the COVID-19 pandemic. The Requirement also infringes CUCOG's members' clinical and professional discretion to adopt policies for their departments that minimize viral exposure risks for patients, physicians, other clinicians, residents, medical students, and staff. CUCOG sues on behalf of its members and its members' patients.

24. For instance, CUCOG member and officer Eve Espey, M.D., M.P.H., FACOG, is a certified mifepristone prescriber under the REMS who prescribes mifepristone for both abortion and miscarriage care to her patients at the University of New Mexico, where Dr. Espey is the chair of the department of obstetrics and gynecology. Many of her patients seeking abortion and miscarriage care are low-income people of color, including a significant Native population, and many live in rural areas. Because of the Mifepristone In-Person Dispensing Requirement, some of Dr. Espey's patients must travel unnecessarily to her health care facility to obtain the mifepristone pill, even when they will be receiving no in-person medical services at that time. The Requirement subjects Dr. Espey, her patients, and the other clinicians and staff in her department, to needless viral exposure risks and other harms, and impedes her from exercising her clinical judgment during the COVID-19 pandemic. If not for the Requirement, some of Dr. Espey's patients could and would obtain mifepristone by mail, without having to make a medically unnecessary trip to her health care facility.

25. Plaintiff **New York State Academy of Family Physicians** ("NYSAFP"), the New York State Chapter of the American Academy of Family Physicians, is a non-profit advocacy organization representing family medicine and family practice physicians throughout New York State in areas of policy, education, clinical and leadership development, and patient engagement, with the goal of improving the quality of family medicine. NYSAFP has over 3,000 practicing physician members and over 500 medical resident members, collectively serving millions of patients. Members practice in almost every county in New York State, in practice settings ranging from New York City to some of the state's most rural counties. NYSAFP's members include physicians who are certified prescribers under the mifepristone REMS and who prescribe mifepristone for abortion and miscarriage care. NYSAFP is headquartered at 16 Sage Estates, Suite 202, Albany, New York 12204.

26. As described *infra*, the Mifepristone In-Person Dispensing Requirement impedes NYSAFP's members' ability to reduce risks of exposure to SARS-CoV-2 for themselves, their staff, and their patients in accordance with their professional judgment, and imposes unnecessary medical risks and other harms on NYSAFP's members and their patients during the COVID-19 pandemic. NYSAFP sues on behalf of its members and its members' patients.

27. For instance, NYSAFP member and board member Heather Paladine, M.D., M.Ed., FAAFP, is a certified mifepristone prescriber under the REMS who prescribes mifepristone to her patients at a "safety net" primary care community health center in New York City exclusively serving uninsured and low-income patients. Because of the Mifepristone In-Person Dispensing Requirement, Dr. Paladine has been unable to provide any medication abortion care to her patients while her office was closed in response to the severe COVID-19 outbreak in New York; although she was continuing to care for other patients via telehealth and could have provided medication

abortion care to eligible patients via telehealth, she did not have a physical location where the patient could obtain the mifepristone in accordance with the Requirement. Her office has reopened at a fraction of its usual capacity, but her ability to see patients needing medication abortion care remains very limited. For those patients she is able to see, the Mifepristone In-Person Dispensing Requirement requires them to travel unnecessarily to her health care facility to obtain the mifepristone pill, even when they will be receiving no in-person medical services at that time. The Requirement thus subjects Dr. Paladine and her patients to needless viral exposure risks and other harms; impedes her from exercising her clinical judgment during the COVID-19 pandemic; and prevents her from providing abortion care to some of her patients at all. If not for the Requirement, some of Dr. Paladine's patients could and would obtain mifepristone by mail, without having to make a medically unnecessary trip to her health care facility.

28. Plaintiff **SisterSong Women of Color Reproductive Justice Collective** ("SisterSong") is a nationwide non-profit membership organization that was formed in 1997 by 16 organizations led by and representing Indigenous, Black, Latinx, and Asian American women and transgender people who recognized their right and responsibility to represent themselves in advancing their needs. By asserting the human right to reproductive justice, SisterSong works to build an effective network of individuals and organizations addressing institutional policies, systems, and cultural practices that limit the reproductive lives of marginalized people. SisterSong's membership includes clinicians who are certified prescribers under the mifepristone REMS and who prescribe mifepristone for abortion and miscarriage care in communities of color, as well as women and trans people of color seeking abortion and miscarriage care.

29. As described *infra,* the Mifepristone In-Person Dispensing Requirement impedes SisterSong's members' ability to reduce risks of exposure to SARS-CoV-2 for themselves, their

staff, and their patients in accordance with their professional judgment, and imposes unnecessary medical risks and other harms on SisterSong's members and their patients during the COVID-19 pandemic. In addition, the Mifepristone In-Person Dispensing Requirement jeopardizes the health and well-being of SisterSong's members seeking reproductive health care by needlessly increasing their risk of contracting COVID-19, which is disproportionately severe and fatal among communities of color. SisterSong sues on behalf of its members and its members' patients. SisterSong is headquartered at 1237 Ralph David Abernathy Blvd., SW, Atlanta, Georgia 30310.

30. For instance, SisterSong member Serina Floyd, M.D., M.S.P.H., FACOG, is a certified mifepristone prescriber pursuant to the REMS who prescribes mifepristone to her patients at Planned Parenthood Metropolitan Washington, D.C., Inc. ("PPMW"), where she serves as the Medical Director and Vice President of Medical Affairs. Because of the Mifepristone In-Person Dispensing Requirement, some of her patients seeking abortion and miscarriage care, who are predominantly low-income people of color, must travel unnecessarily to PPMW's clinics in Maryland and Washington, D.C., to obtain their mifepristone pill, even when they will be receiving no in-person medical services at that time. The Requirement subjects Dr. Floyd, her staff, and her patients to needless viral exposure risks and other harms, and impedes her from exercising her clinical judgment during the COVID-19 pandemic. If not for the Requirement, some of Dr. Floyd's patients could and would obtain mifepristone by mail, without having to make a medically unnecessary trip to her health care facility.

31. Plaintiff **Honor MacNaughton**, M.D., is a certified mifepristone prescriber under the REMS who prescribes mifepristone to her patients at a "safety net" hospital system in the greater Boston area that serves predominantly low-income patients. Because of the Mifepristone In-Person Dispensing Requirement, some of Dr. MacNaughton's patients seeking abortion and

miscarriage care must travel unnecessarily to her health care facility to obtain their mifepristone pill, even when they will be receiving no medical services at that time. The Requirement subjects Dr. MacNaughton and her patients to needless viral exposure risks and other harms, and impedes her from exercising her clinical judgment during the COVID-19 pandemic. If not for the Requirement, some of Dr. MacNaughton's patients could and would obtain mifepristone by mail, without having to make a medically unnecessary trip to her health care facility. Dr. MacNaughton sues in her individual capacity and not as a representative of any institution with which she is affiliated. Dr. MacNaughton's address is P.O. Box 400865, Cambridge, Massachusetts 02140.

Defendants

32. Defendant **FDA** is an agency of the United States government within HHS, headquartered in Silver Spring, Maryland. The Secretary of HHS has delegated to the FDA the authority to administer the provisions of the Food, Drug, and Cosmetic Act ("FDCA") authorizing the imposition of a REMS. *See* 21 U.S.C. § 355-1(a)(4).[1] The FDA promulgated the mifepristone REMS that includes the In-Person Dispensing Requirement, and has maintained the Mifepristone In-Person Dispensing Requirement despite numerous requests from Plaintiffs and other medical authorities for relief from this mandate during the COVID-19 pandemic.

33. Defendant **Stephen Hahn**, M.D., who is being sued in his official capacity only, is the Commissioner of Food and Drugs and is responsible for supervising the activities of the FDA, including with regard to the imposition, suspension, waiver, or removal of a REMS. Defendant Hahn maintains offices in Silver Spring, Maryland, and in Washington, D.C. Defendant Hahn has

[1] *See also* U.S. Food & Drug Admin., FDA Staff Manual Guides, Volume II - Delegations of Authority 1410.10(1)(A)(1) (effective Aug. 26, 2016), https://www.fda.gov/media/81983/download (delegations of authority to the Commissioner of Food and Drugs).

presided over the FDA while it has maintained the Mifepristone In-Person Dispensing Requirement during the COVID-19 pandemic.

34. Defendant **HHS** is a cabinet-level department of the United States government with offices in Washington, D.C. Its components include the FDA, CDC, and numerous others. HHS is responsible for enhancing and protecting the health and well-being of all Americans by providing for effective health and human services and fostering advances in medicine, public health, and social services. HHS is the principal cabinet-level department responsible for coordinating the federal government's response to the COVID-19 pandemic, including with regard to the imposition, suspension, waiver, or removal of federal requirements relating to the use of telemedicine.

35. Defendant **Alex Azar**, J.D., who is being sued in his official capacity only, is the Secretary of HHS and is responsible for administering and enforcing REMS programs, in consultation with the office responsible for reviewing a drug and the office responsible for post-approval safety within the FDA, as well as for overseeing HHS's response to the COVID-19 pandemic. Defendant Azar maintains an office in Washington, D.C.

FACTUAL ALLEGATIONS

Mifepristone Regimen and Safety

Medication Abortion Regimen

36. Medication abortion to end an early pregnancy involves two FDA-approved prescription medications: mifepristone and misoprostol. Together, they cause the patient to undergo a pregnancy termination within a predictable period of time in a manner that is clinically very similar to an early miscarriage.

37. To date, more than four million people in the United States have used mifepristone

in combination with misoprostol to end an early pregnancy.[2] The mifepristone-misoprostol combination comprised 39% of all U.S. abortions in 2017 (the latest available data).[3]

38. The mifepristone-misoprostol regimen is as follows: *First*, the prescribing clinician assesses the patient's eligibility for a medication abortion. Sometimes this will occur through an in-person assessment, such as an ultrasound and/or blood work, and sometimes entirely through telehealth (for patients with regular periods and no risk factors) based on the patient's reported results of an over-the-counter urine pregnancy test(s), last menstrual period ("LMP"), medical history, and a discussion of any symptoms she is experiencing.

39. The FDA does not dictate where or how this eligibility assessment is conducted; it is left to the clinician's best medical judgment and may occur entirely through telehealth technologies. Indeed, during the pandemic, Plaintiff ACOG issued guidance specifically recommending that clinicians consider performing these assessments remotely.[4]

40. If, based on a remote evaluation, the patient is eligible for a medication abortion without an in-person assessment, the clinician will comprehensively counsel the patient about the risks of, and alternatives to, the medication abortion regimen, including reviewing certain information required by the mifepristone REMS. The prescriber then obtains the patient's

---

[2] *Mifeprex Effectiveness & Advantages*, Danco Laboratories, https://www.earlyoptionpill.com/is-mifeprex-right-for-me/effectiveness-advantages/ (last visited May 23, 2020).

[3] Rachel K. Jones, Elizabeth Witwer & Jenna Jerman, *Abortion Incidence and Service Availability in the United States, 2017*, Guttmacher Inst., at 8 (Sept. 2019), https://www.guttmacher.org/report/abortion-incidence-service-availability-us-2017.

[4] *See COVID-19 FAQs for Obstetrician-Gynecologists, Gynecology*, Am. Coll. of Obstetricians & Gynecologists [hereinafter "ACOG"], https://www.acog.org/en/clinical-information/physician-faqs/COVID19-FAQs-for-Ob-Gyns-Gynecology (last visited May 23, 2020) (COVID-19 guidance explicitly instructing health care providers to consider assessing how many weeks the pregnancy has advanced "remotely for patients with regular periods, a known last menstrual period, and no risk factors for ectopic pregnancy. An ultrasound assessment is not required.")

informed consent.

41. If the patient is eligible for and has consented to a medication abortion, the clinician issues a prescription for mifepristone and misoprostol. The patient is given specific instructions for use and follow-up care, including how to identify and obtain care in the extremely rare event of a serious complication.

42. *Second*, the patient picks up their prescription for mifepristone—a single 200 mg tablet—at the prescriber's hospital, clinic, or medical office. Because of the Mifepristone In-Person Dispensing Requirement, discussed further *infra*, the patient must travel in person to the health care facility to obtain this pill, even if the eligibility assessment was completed through telehealth or at an earlier visit and they are obtaining no in-person services. The patient will also sign a form required by the mifepristone REMS containing the same information the prescriber and patient have previously reviewed, which, incidental to the Mifepristone In-Person Dispensing Requirement, must be signed onsite.

43. *Third*, the patient takes the mifepristone orally. The FDA allows patients to swallow the mifepristone wherever they feel most comfortable, including at home.

44. *Fourth*, 24 to 48 hours later, and also at a location of their choosing, the patient takes the misoprostol. The patient may obtain the misoprostol from a mail-order or retail pharmacy, or at the health care facility where they obtained the mifepristone.

45. *Fifth*, approximately 2 to 24 hours after taking the misoprostol, the patient will experience bleeding and cramping that expels the pregnancy. The FDA's labeling for mifepristone advises prescribers to discuss with patients where they will be located beginning 2 hours after taking the misoprostol (*i.e.*, 26 to 50 hours after taking the mifepristone) to ensure they are in a comfortable location for this expected bleeding and cramping.

46. *Finally*, the FDA advises patients to follow up with their prescriber 7 to 14 days after completing the medication abortion regimen to ensure the abortion was successful. This follow-up often occurs by phone, with termination of pregnancy confirmed by self-reported symptoms and a home urine pregnancy test.

47. When used in a medication abortion, mifepristone blocks the body's receptors for progesterone, a hormone necessary to sustain pregnancy, causing the pregnancy tissue and lining of the uterus to break down and separate from the uterine wall.

48. Misoprostol causes uterine contractions that expel the contents of the uterus. Although misoprostol taken alone also acts as an abortifacient, it is far more effective when used in combination with mifepristone.

49. The FDA-approved labeling for mifepristone indicates that the mifepristone-misoprostol regimen is for use through 70 days LMP. However, for *all* medications, evidence-based "off-label" use is common, permissible, and often essential to align with evolving standards of care. The mifepristone-misoprostol regimen is now increasingly prescribed through 77 days (11 weeks) LMP in accordance with research confirming the safety and efficacy of medication abortion beyond 10 weeks of pregnancy.

Early Pregnancy Loss (Miscarriage) Regimen

50. While misoprostol alone has long been used to medically manage early pregnancy loss, it is now widely recognized that the superior miscarriage treatment regimen includes mifepristone. Mifepristone enhances the efficacy of the misoprostol, making it more likely that the patient will completely expel the pregnancy with medications alone and decreasing the need for a follow-up in-office procedure to evacuate the uterus.

51. Patients experiencing early pregnancy loss frequently do not obtain treatment when

and where they first receive the miscarriage diagnosis. Patients often want additional time to process the diagnosis, or to wait and see if the miscarriage resolves on its own, before deciding to undergo medical treatment. In addition, pregnant patients who present to an emergency department with bleeding or pain and receive a miscarriage diagnosis are particularly likely to be referred elsewhere for treatment during the pandemic, when hospital resources are stretched thin and exposure risks increase the longer a patient spends in the hospital.

Safety of Mifepristone

52. According to the FDA, "Mifeprex has been increasingly used as its efficacy and safety have become well established by both research and experience, and serious complications have proven to be extremely rare."[5] The FDA has observed that "[m]ajor adverse events . . . are reported rarely in the literature on over 30,000 patients. The rates, when noted, are exceedingly rare, generally far below 0.1% for any individual adverse event."[6]

53. The specific serious complications identified in the FDA-approved labeling for Mifeprex are "Serious and Sometimes Fatal Infections or Bleeding." The labeling specifies that such "serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion or childbirth"—i.e., any time the pregnant uterus is emptied—and that "[n]o causal relationship between the use of MIFEPREX and

[5] U.S. Food and Drug Admin., Ctr. for Drug Evaluation & Res., *Medical Review of Mifeprex* 12 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf [hereinafter "FDA 2016 Medical Review"]; *see also* U.S. Food & Drug Admin., Full Prescribing Information for Mifeprex 7–8, Tables 1 & 2 (approved Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf [hereinafter "Mifeprex Labeling"], attached hereto as Exhibit 1.

[6] FDA 2016 Medical Review, *supra* note 5, at 47; *see also* Mifeprex Labeling, *supra* note 5, Ex. 1 at 8, Table 2.

misoprostol and [infections and bleeding] has been established."[7]

54. Carrying a pregnancy to term poses much higher risks of both morbidity and mortality than medication abortion. In the United States, a person is approximately 14 times more likely to die if they continue a pregnancy to term rather than have an abortion.[8]

FDA Regulation of Mifepristone

55. The FDA imposed the Mifepristone In-Person Dispensing Requirement in 2000, when it first approved mifepristone for marketing in the United States.[9] Since 2011, this restriction (and others) have been imposed under the FDA's "REMS" authority.[10]

56. Leading medical authorities, including Plaintiff ACOG, have long opposed the Mifepristone In-Person Dispensing Requirement as medically unnecessary and burdensome.[11]

57. A REMS is a set of restrictions beyond the drug's labeling that the FDA may impose only when necessary to ensure that a drug's benefits outweigh its risks. 21 U.S.C. § 355-1(a)(1).

58. The most burdensome type of REMS are "Elements to Assure Safe Use"

---

[7] Mifeprex Labeling, *supra* note 5, Ex. 1 at 2, 16.
[8] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119(2) Obstetrics & Gynecology 215, 216 (Feb. 2012).
[9] *See* U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, *Risk Assessment and Risk Mitigation Review(s)* 7 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RiskR.pdf [hereinafter "FDA 2016 REMS Review"]. Because this document is a package of memoranda and letters, each with page numbers beginning at 1, Plaintiffs' pin-cites refer to the page number within the 37-page PDF.
[10] *Id.*
[11] *See* U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, *Cross-Discipline Team Leader Review* 25 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020CrossR.pdf (discussing letters submitted by ACOG, the American Public Health Association, and other medical and public health authorities asking FDA to eliminate the mifepristone REMS, including the in-person dispensing requirement).

("ETASU"), which the FDA may properly impose on a drug that "has been shown to be effective" only if it is "associated with a serious adverse drug experience" such that it "can be approved only if, or [approval] would be withdrawn unless, such elements are required." *Id.* § 355-1(f)(1)(A).

59. The mifepristone REMS contains three ETASU:[12]

60. *First*, the **In-Person Dispensing ETASU** ("ETASU C," pursuant to 21 U.S.C. § 355-1(f)(3)(C)) provides that mifepristone may be dispensed only in a hospital, clinic, or medical office, by or under the supervision of a "certified prescriber" (defined *infra*). Patients may not obtain mifepristone by prescription from a mail-order or retail pharmacy as they would for virtually any other drug, nor even receive the medication directly by mail from their prescriber where state law allows. Instead, patients must fill their prescription only at a hospital, clinic, or medical office, even when—as the REMS permits—they are receiving no other in-person services at that time and will swallow the pill at home. Of the 16 drugs subject to ETASU C, mifepristone is the only one for which patients may self-administer the medication without clinical supervision.

61. *Second*, **Prescriber Certification ETASU** ("ETASU A," pursuant to 21 U.S.C. § 355-1(f)(3)(A)) requires that clinicians who seek to prescribe mifepristone fax to the drug distributor a form attesting to their clinical abilities; agreeing to comply with certain reporting requirements; and agreeing to comply with the other REMS elements.

62. *Third*, the **Patient Form ETASU** ("ETASU D," pursuant to 21 U.S.C. § 355-1(f)(3)(D)) provides that the prescriber and patient must review and sign a special form containing information regarding the mifepristone regimen and risks, and that the prescriber provide the

[12] U.S. Food & Drug Admin., Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200mg (Apr. 2019), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2019_04_11_REMS_Full.pdf [hereinafter "Mifepristone REMS"], attached hereto as Exhibit 2.

patient with a copy of the form and place a copy of the form in the patient's chart. All of the information in the patient form is also included in the "Medication Guide" that is part of the FDA-approved labeling for mifepristone that is provided to patients with the medication. Indeed, in 2016, the FDA's multidisciplinary expert review team and the Director of the FDA's Center for Drug Evaluation and Research recommended eliminating the Patient Form Requirement Agreement because it is "duplicative of information in the Medication Guide," "does not add to safe use conditions," and "is a burden for patients," but they were overruled by the FDA Commissioner.[13]

63. Both the Prescriber Certification and the Patient Form Requirement contain language assuming that the prescriber and patient are in the same physical location. The Patient Form, which must be signed by both the patient and the prescriber, states that the patient signed the form "in my [the prescriber's] presence after I counseled her and answered all her questions," and that the prescriber must "give 1 copy [of the form] to the patient before she leaves the office and put 1 copy in her medical record."[14] The Prescriber Certification echoes this language and also requires that the clinician "record the serial number from each package of Mifeprex in each patient's record."[15] These requirements are incidental to the In-Person Dispensing Requirement and encompassed by Plaintiffs' use of the term herein.

64. There is no requirement that the prescriber review the Patient Form and answer any questions immediately before the patient signs: prescribers may and do conduct such counseling via telehealth and then simply obtain a signature when the patient presents at the hospital, clinic,

[13] FDA 2016 REMS Review, *supra* note 9, at 2; U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Res., *Summary Review* 25 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020SumR.pdf
[14] Mifepristone REMS, *supra* note 12, Ex. 2 at 8.
[15] *Id.* at 6.

or medical office to pick up their prescription.

65. The requirement that the prescriber record the package serial number is a function of the extremely unusual requirement for mifepristone that the prescriber also act as the pharmacist, dispensing the medication onsite. There is no medical rationale for requiring the prescriber (as opposed to a pharmacist) to record the serial number.

66. Under the FDCA, the federal government can enforce a REMS against individual clinicians or against the drug sponsor. *Id.* §§ 331, 333, 352(y), 355-1(b)(7). Penalties against a drug sponsor for REMS violations can include an injunction preventing the manufacturer from any further sales or distribution of the product and/or seizure of product. *Id.* §§ 331, 352(y). The manufacturer can also be subject to civil penalties (up to $250,000 per REMS violation), as well as criminal penalties, and other forms of potential liability. *Id.* §§ 333(f)(4)(A), 334.

COVID-19 in the United States

Current Impact of the Pandemic

67. COVID-19 is the disease caused by the SARS-CoV-2 virus that was first reported to the World Health Organization ("WHO") on December 31, 2019.[16] In less than three months, COVID-19 spread across the world, causing the WHO to label the outbreak a "global pandemic" on March 11, 2020.[17] At that time, there were 118,000 cases in 110 countries. As of May 20, the WHO reported nearly 5 million confirmed cases and more than 320,000 confirmed deaths across 216 countries, areas, and territories.[18]

68. As of May 20, four months since the first confirmed case of SARS-CoV-2 on U.S.

---

[16] *WHO Timeline -- COVID 19*, World Health Org., https://www.who.int/news-room/detail/27-04-2020-who-timeline---covid-19 (last visited May 20, 2020).
[17] *Id.*
[18] *Coronavirus Disease (COVID-19) Pandemic*, World Health Org., https://www.who.int/emergencies/diseases/novel-coronavirus-2019 (last visited May 20, 2020).

soil, the CDC reported more than 1.5 million cases and nearly 100,000 deaths in the United States, with cases in every state and the District of Columbia.[19] Those numbers mark the highest number of COVID-19 cases and related deaths in any country in the world.[20] Indeed, the case and death tally in certain U.S. *states* exceeds that of most countries in the world.[21]

69. As of May 20, more than 23,000 new cases and more than 1,300 new deaths in a single day were being reported in the United States, as the overall impact of the pandemic continues to increase here.[22]

70. Significantly, COVID-19's harms have not been borne equally. The available data show a particularly high prevalence of infection in areas with lower average incomes, which often overlap with areas where a higher percentage of people of color live.

71. This higher prevalence is likely due to the fact that many people with lower-paying employment have neither the flexibility to work from home nor the financial cushion to forgo working, and often work in essential jobs (for instance, as home health aides or grocery store clerks) in which the infection prevention measures described *infra*—namely, maintaining at least six feet of distance from other people—are difficult or impossible. People with fewer resources are also more likely to live in crowded housing, without extra space that might allow isolation of a family member sick with COVID-19; more likely to rely on public transportation; and generally lack the resources available in wealthier communities to mitigate the risk of contagion.

---

[19] *Cases in the U.S.*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html (last visited May 20, 2020).

[20] *See WHO Coronavirus Disease (COVID-19) Dashboard*, World Health Org., https://covid19.who.int/ (last visited May 20, 2020).

[21] *Compare id.*, *with United States COVID-19 Cases and Deaths by State*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/covid-data-tracker/index.html (last visited May 20, 2020).

[22] *Cases in the U.S.*, *supra* note 19.

72. In addition, due to longstanding inequities in access to and quality of care and structural racism, low-income people and people of color are more likely to suffer from certain preexisting medical conditions, such as diabetes, obesity, and hypertension, that make them high-risk for severe COVID-19 illness and fatality.

73. For instance, in the 28 states and New York City reporting race and ethnicity with COVID-19 mortality data, and after adjusting for age, Black Americans are more than 3.5 times as likely to die from COVID-19, and Latinx Americans are almost twice as likely to die, as white Americans.[23] Black Americans represent only about 13% of the population in the states reporting racial/ethnic information, but account for about 34% of total COVID-19 deaths in those states.[24]

Ongoing Nature of the Pandemic

74. The virus will stop spreading only once there is "herd immunity," which occurs when a sufficiently high percentage of the population becomes immune to an infectious disease, such that the spread is dramatically slowed. In this context, an individual's immunity can come from either a vaccine or from previous infection.

75. There is no COVID-19 vaccine, and it is unlikely that an FDA-approved vaccine will be available for widespread public use for approximately 12 to 18 months. Even when a vaccine is available, there may be limited quantities and additional time necessary to manufacture and distribute the necessary supply.

76. Moreover, due to the virus's novelty, it is still unknown whether any immunity generated by previous infection lasts permanently or only for a specified period, or whether some

[23] Cary P. Gross, Utibe R. Essien, Saamir Pasha, Jacob R. Gross, Shi-yi Wang & Marcella Nunez-Smith, *Racial and Ethnic Disparities in Population Level Covid-19 Mortality*, medRxiv, https://doi.org/10.1101/2020.05.07.20094250

[24] *Racial Data Transparency*, Johns Hopkins Univ., https://coronavirus.jhu.edu/data/racial-data-transparency (last visited May 24, 2020).

individuals who have had the virus do not develop immunity at all. Even assuming that infection confers permanent or long-term immunity, and even in places already hit hard by the COVID-19 pandemic, such as New York City, the data show that the population is very far from obtaining herd immunity based on prior infection alone.

77. As a result, SARS-CoV-2 transmission is likely to continue across the United States throughout 2020 and into at least 2021, until the development and widespread use of a vaccine.

78. The COVID-19 pandemic may have an even more severe impact in fall 2020 and winter 2021 because of the overlapping effects of influenza and respiratory syncytial virus, which peak seasonally in the fall and winter and produce many of the same symptoms as COVID-19.

79. In short, a diminishing number of new cases identified or deaths recorded per day, or a "flattening of the curve," does not mean the end of COVID-19 or diminished harms for the individuals who will continue to become infected. It also does not prevent a new spike in the number of cases, which is expected as some businesses and schools begin to resume in-person services and the number of in-person encounters increases.

Infection Prevention Measures

80. The only known effective measure to reduce the risk of serious illness and death from COVID-19 is to prevent infection in the first place.

81. Transmission of SARS-CoV-2 can occur in any location where there is close proximity (less than six feet) between individuals. Because transmission of the virus can occur via environmental surfaces, there is also risk of spread of the virus at any location where multiple individuals touch surfaces. There is also growing evidence that the virus can become aerosolized and linger in the air after an infected person talks or coughs, for instance, and then leaves the area.

82. Accordingly, the CDC and other public health experts have identified staying at

home, avoiding close contact with other individuals (i.e., "social distancing"), and adopting a vigilant hygiene regimen, as the best measures for protecting against transmission of SARS-CoV-2. Because the virus spreads even among people who do not feel sick or exhibit any symptoms, reducing in-person encounters is the best way to curb transmission.

Federal Actions Encouraging Telehealth and Giving Clinicians Discretion to Forgo Unnecessary In-Person Encounters During the COVID-19 Pandemic

83. One critical way to decrease potential in-person contacts is through greater use of telemedicine. By reducing in-person visits to medical offices and hospitals, telemedicine helps reduce the risks patients face when traveling for care, while also preventing health care facilities from becoming sites of transmission. Telemedicine enables clinicians to meet patients' time-sensitive medical needs remotely, preventing delays in care that would lead to worse health outcomes and/or necessitate more intensive treatment down the road.

84. Defendant HHS has emphatically promoted the widespread use of telemedicine during the pandemic. The CDC instructs health care professionals that "[l]everaging telemedicine whenever possible is the best way to protect patients and staff from COVID-19,"[25] and encourages patients to "[u]se telemedicine, if available, or communicate with your doctor or nurse by phone or e-mail."[26] The CDC specifically advises patients to use mail-order or delivery services, if possible, for all of their prescriptions.[27]

85. To facilitate an expansion of telehealth, Defendant HHS's Office for Civil Rights

[25] *Coronavirus Disease 2019 (COVID 19): Preparedness Tools, Print Resources*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/coronavirus/2019-ncov/hcp/preparedness-resources.html (last updated Mar. 31, 2020).
[26] *Coronavirus Disease 2019 (COVID 19): Daily Life & Coping, Running Essential Errands*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/essential-goods-services.html (last updated May 11, 2020) [hereinafter "CDC, *Running Essential Errands*"].
[27] *Id.*

("OCR") announced that it would waive potential penalties under the Health Information and Privacy Protection Act against health care providers that act in "good faith" to serve patients through everyday communications technologies, such as FaceTime or Zoom, during the COVID-19 emergency. The OCR Director explained: "We are empowering medical providers to serve patients wherever they are during this national public health emergency."[28]

86. Another HHS agency, the Centers for Medicare and Medicaid Services ("CMS"), announced in March that it would temporarily expand Medicare coverage to include a broader range of telemedicine services,[29] and in April published a toolkit to help states take advantage of "broad federal flexibility to cover telehealth through Medicaid."[30] CMS Administrator Seema Verma explained that the coverage expansion would allow patients "to communicate with their doctors without having to travel to a healthcare facility so that they can limit risk of exposure and spread of this virus. Clinicians on the frontlines will now have greater flexibility to safely treat our beneficiaries."[31] Defendant Secretary Azar similarly stated that the coverage expansion would allow patients "to access healthcare they need from their home, without worrying about putting

[28] *OCR Announces Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency*, Health & Human Servs. (Mar. 17, 2020), https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html.
[29] *President Trump Expands Telehealth Benefits for Medicare Beneficiaries During COVID-19 Outbreak*, Ctrs. for Medicare & Medicaid Servs. (Mar. 17, 2020), https://www.cms.gov/newsroom/press-releases/president-trump-expands-telehealth-benefits-medicare-beneficiaries-during-covid-19-outbreak.
[30] *Trump Administration Released COVID-19 Telehealth Toolkit to Accelerate State Use of Telehealth in Medicaid and* CHIP, Ctrs. for Medicare & Medicaid Servs. (Apr. 23, 2020), https://www.cms.gov/newsroom/press-releases/trump-administration-releases-covid-19-telehealth-toolkit-accelerate-state-use-telehealth-medicaid.
[31] *Id.*

themselves or others at risk during the COVID-19 outbreak."[32]

87. Defendant FDA has likewise encouraged the use of telemedicine. For example, the agency issued guidance in March, under its authority to "protect[] the United States from threats . . . including the . . . COVID-19 pandemic," that sought to expand the use of remote patient monitoring devices.[33] As the FDA explained: "In the context of the COVID-19 public health emergency, the leveraging of current non-invasive patient monitoring technology will help eliminate unnecessary patient contact and ease the burden on hospitals, other health care facilities, and health care professionals that are experiencing increased demand due to the COVID-19 pandemic as it relates to diagnosis and treatment of patients with COVID-19 and ensuring other patients who require monitoring for conditions unrelated to COVID-19 can be monitored outside of health care facilities."[34]

88. Defendants have also relaxed in-person requirements for highly regulated drugs during the pandemic, to afford clinicians discretion to provide appropriate medical care under these emergency circumstances. On March 22, 2020, the FDA issued guidance declaring its intention not to enforce REMS requirements for laboratory testing (such as liver enzyme testing) or imaging studies (such as MRIs) for the duration of the public health emergency, as long as the decision to forgo testing was made based on the judgment of a health care professional.[35]

---

[32] *Secretary Azar Announces Historic Expansion of Telehealth Access to Combat COVID-19*, Health & Human Servs. (Mar. 17, 2020), https://www.hhs.gov/about/news/2020/03/17/secretary-azar-announces-historic-expansion-of-telehealth-access-to-combat-covid-19.html.

[33] U.S. Food & Drug Admin., Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: Guidance for Industry and Food and Drug Administration Staff (Mar. 2020), https://www.fda.gov/media/136290/download.

[34] *Id*.

[35] U.S. Food & Drug Admin., Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency: Guidance for Industry and Health Care Professionals (Mar. 2020),

89. In announcing its intent not to enforce other REMS, the FDA stated that, during the COVID-19 emergency, "completion of REMS-required laboratory testing or imaging studies may be difficult because patients may need to avoid public places and patients suspected of having COVID-19 may be self-isolating and/or subject to quarantine. Under these circumstances, undergoing laboratory testing or imaging studies in order to obtain a drug subject to a REMS can put patients and others at risk for transmission of the coronavirus."[36]

90. Similarly, Defendant Secretary Azar lifted in-person requirements for the prescription of controlled substances during the public health emergency. In consultation with the U.S. Drug Enforcement Agency ("DEA"), Defendant Azar has activated an emergency exception that allows medical providers to prescribe controlled substances via telemedicine without first conducting an in-person examination.[37] In a letter to practitioners, the DEA also explained that it is "exercising its authorities to provide flexibility in the prescribing and dispensing of controlled substances to ensure necessary patient therapies remain accessible" during the nationwide public health emergency declared by HHS as a result of COVID-19.[38] The head of the DEA stated that the agency would continue to "explore options that ensure those in need of vital prescriptions are able to get them, while still adhering to safe practices such as social distancing."[39]

---

https://www.fda.gov/media/136317/download [hereinafter "FDA Policy for Certain REMS During COVID-19"].

[36] *Id.* at 7.

[37] *COVID-19 Information Page, Telemedicine*, U.S. Drug Enf't Admin., https://www.deadiversion.usdoj.gov/coronavirus.html#TELE (last visited May 25, 2020).

[38] U.S. Drug Enf't Admin., Letter from Thomas Prevoznik to U.S. Drug Enf't Admin. Qualifying Practitioners and U.S. Drug Enf't Admin. Qualifying Other Practitioners (Mar. 31, 2020), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf

[39] *DEA's Response to COVID-19*, U.S. Drug Enf't Admin. (Mar. 20, 2020), https://www.dea.gov/press-releases/2020/03/20/deas-response-covid-19.

91. In accordance with public health guidance and this easing of federal restrictions, clinicians are embracing health care delivery models that meet patients' urgent needs while reducing unnecessary travel and in-person examinations. In particular, in virtually all areas of health care, clinicians are using telemedicine where medically appropriate to evaluate and treat patients during the pandemic.

92. From management of chronic conditions, to acute treatment of infections, to prenatal care, clinicians are using their professional judgment to care for patients remotely during this public health emergency.

93. Without the increased use of telemedicine, many more patients would be going without necessary health care during this pandemic, and many more patients and health care staff would needlessly face increased transmission risks associated with in-person health care visits.

FDA's Retention of the Mifepristone In-Person Dispensing Requirement Despite Entreaties from Medical Authorities for Relief During the Pandemic

94. Recognizing the harm that the Mifepristone In-Person Dispensing Requirement is causing patients and clinicians, particularly during the COVID-19 pandemic, and the lack of any basis for the FDA's differential treatment of mifepristone prescribers and patients, for the past two months leading medical and public health experts have petitioned the FDA not to enforce the Requirement during the COVID-19 pandemic against clinicians exercising their professional judgment to appropriately mitigate burdens and risks for their patients.

95. These requests include (but are not limited to):

- The American Academy of Family Physicians (March 25, 2020);[40]
- Nine clinics providing abortion and other reproductive health services in 16

[40] Letter from John S. Cullen, M.D., FAAFP, Am. Academy of Family Physicians, to Stephen M. Hahn, M.D., U.S. Food & Drug Admin. (Mar. 25, 2020), attached hereto as Exhibit 3.

states (March 27, 2020);[41]

- ACOG and the Society for Maternal-Fetal Medicine (April 20, 2020);[42] and
- Dozens of professional associations and institutions, including Abortion Care Network, American Society for Reproductive Medicine, American College of Nurse-Midwives, Maryland Academy of Family Physicians, Massachusetts Academy of Family Physicians, Michigan Academy of Family Physicians, Minnesota Academy of Family Medicine, National Abortion Federation, NYSAFP, Planned Parenthood Federation of America, Reproductive Health Access Project, WAFP, and Weill Cornell Medicine, as well as hundreds of individual clinicians and researchers from many of the nation's leading universities (April 28, 2020).[43]

96. Despite these urgent requests reflecting the national medical consensus that the Requirement is needlessly harming patients and clinicians during this crisis, Defendants failed to withdraw, suspend, or declare an intention not to enforce the Requirement during the pandemic, and failed to provide any explanation for their constructive denial of these requests.

FDA's Discriminatory Treatment of Mifepristone Prescribers and Patients with No Medical Basis

97. There is no medical basis for requiring a patient to whom mifepristone has been prescribed to travel to a hospital, clinic, or medical office solely to obtain a medication (which the patient is permitted to swallow later at home) and physically sign a form (which the patient has already reviewed with their prescriber via telehealth) during the pandemic.

98. Of the more than 20,000 FDA-approved drug products, the FDA subjects only 16 drugs to a REMS requiring the patient to obtain the medication in a hospital, clinic, or medical office—two of which are Mifeprex and its generic, mifepristone. For every one of these 16 drugs

[41] Letter from Affiliated Med. Servs. et al., to Janet Woodcock, M.D., U.S. Food & Drug Admin. (Mar. 27, 2020), attached hereto as Exhibit 4.
[42] Letter from ACOG & the Society for Maternal-Fetal Medicine to Stephen M. Hahn, M.D., U.S. Food & Drug Admin. (Apr. 20, 2020), attached hereto as Exhibit 5.
[43] Letter from Public Health Experts and Advocates to Janet Woodcock, M.D., U.S. Food & Drug Admin. (Apr. 28, 2020), attached hereto as Exhibit 6.

except Mifeprex and its generic, either the method by which the drug is administered requires, or the drug's prescribing information specifically states, that the drug is administered only in certain health care settings or by specified health care personnel. Mifeprex and its generic are the *only* FDA-approved drugs for which the FDA regulates where the patient can obtain the drug, but neither specifies where the patient must take it nor requires any supervision of the patient as the drug is administered.

99. Indeed, in 2016, the FDA updated the Mifeprex labeling to indicate that patients may take the mifepristone without clinical supervision at a location of their choosing, based on "studies, including those of home use of mifepristone and misoprostol, [that] show increased convenience, autonomy and privacy for the woman, . . . and no increased burden on the health care system," and that identify "safety" as among the benefits of home administration.[44]

100. Moreover, the pharmacologic effects of mifepristone do not begin until hours after ingestion, and, as the labeling explains, "most women will expel the pregnancy within 2 to 24 hours of taking *misoprostol*"—i.e., 26 to 72 hours after taking the mifepristone.[45] Thus, regardless of where patients take the mifepristone, they will almost never be with their prescriber by the time they experience the medication's effects. The Mifepristone In-Person Dispensing Requirement has no bearing on whether a patient will experience one of the "exceedingly rare" risks listed in the labeling, nor on how such a rare complication would be managed.

101. While the FDA refuses to allow clinicians prescribing mifepristone for abortion or miscarriage care to mail mifepristone directly to their patients or call in a prescription to a mail-order pharmacy, even during this pandemic, FDA has long authorized the same chemical

[44] FDA 2016 Medical Review, *supra* note 13, at 62.
[45] Mifeprex Labeling, *supra* note 5, Ex. 1 at 3.

compound to be mailed directly to patients' homes in far greater quantities when used for a different purpose.

102. Mifepristone is also FDA-approved for marketing under the brand name Korlym® in 300 mg tablets for daily use by patients with endogenous Cushing's syndrome to treat high blood sugar caused by high cortisol levels in the blood. Korlym is *not* subject to a REMS and may be obtained from a mail-order pharmacy that delivers the drug to the patient's home. The patient then takes one to four pills (300 mg to 1200 mg—1.5 to 6 times the recommended dose for Mifeprex) daily at home according to their prescription. In 2016, the FDA observed that "Korlym is taken in higher doses, in a chronic, daily fashion unlike the single 200 mg dose of Mifeprex that is the subject of this supplement; the rate of adverse events with Mifeprex is much lower."[46]

103. There is no medical basis for allowing a mail-order pharmacy to dispense Korlym to patients by prescription under all circumstances but prohibiting a mail-order pharmacy from dispensing mifepristone by prescription even during the COVID-19 pandemic.

104. The FDA also allows the mailing of misoprostol, the second drug in the FDA-approved medication abortion regimen. Misoprostol is not subject to a REMS and patients may obtain it from retail or mail-order pharmacies.

105. Defendants have singled out mifepristone prescribers and patients for a special barrier to telehealth care during the COVID-19 pandemic that impedes clinicians' medical judgment; subjects patients, clinicians, and other health care staff to unnecessary medical risks; serves no rational or legitimate government purpose; and conflicts with Defendants' own efforts to mitigate the spread of COVID-19.[47]

[46] Mifeprex Medical Review, *supra* note 5, at 10.
[47] FDA Policy for Certain REMS During COVID-19, *supra* note 35, at n.13.

The Impact of the In-Person Dispensing Requirement During COVID-19

106. Because of the Mifepristone In-Person Dispensing Requirement, Plaintiffs and their members must force patients to travel in person to a hospital, clinic, or medical office during the COVID-19 pandemic, even when the patient has already been evaluated and comprehensively counseled during a telehealth consultation or prior in-person evaluation and there is no medical reason to make the in-person trip.

107. The Requirement increases SARS-CoV-2 exposure risks for patients and clinicians in at least three ways: *first*, by directly requiring travel and person-to-person contact as a condition of obtaining mifepristone for abortion or miscarriage care; *second*, by forcing patients to raise funds and make arrangements for such travel and childcare, which—particularly in the context of the pandemic and associated economic crisis—will delay some patients to the point in pregnancy when medication abortion is no longer available and they instead need an in-office procedure that requires more person-to-person contact for a longer duration of time; and *third*, by causing some patients to use a less effective miscarriage treatment regimen (without mifepristone) in order to try and minimize exposure risks and travel burdens, but which ultimately makes it more likely that they will need a subsequent in-office procedure.

108. Traveling during the pandemic imposes medical risks. Many patients, and particularly patients who are low-income, use public transportation, ride-sharing, or a borrowed car, all of which expose the patient to risks of infection from surfaces and from other individuals from whom they cannot maintain six feet of separation. If the patient has a car, stopping for gas or a restroom on the way to the health care facility also creates infection risk. Given the dearth of abortion access in many areas of the country and the frequency with which patients must travel significant distances for such care, these stops necessarily occur for many patients. Indeed, 89%

of U.S. counties lacked an abortion clinic in 2017 (the latest available data).[48]

109. In addition to being a significant cost and logistical hurdle, this poses significant viral exposure risks. Indeed, it is exceedingly difficult to find childcare during the COVID-19 pandemic precisely because of the viral exposure risks, which have prompted many schools, camps, and daycares to close and disrupted the social networks on which people typically rely. Many health care facilities are not permitting children into their facilities during this pandemic (unless being treated directly) because of social distancing and infection prevention efforts. Many patients, therefore, will have to either allow caregivers into their homes or drop their children off at someone else's home (assuming they are able to find someone willing and able to risk the exposure) or leave their children at a childcare facility (if they even have access to, and can afford care at, a facility that is still open), while they travel to the health care center to obtain the mifepristone—expanding contacts that occur without social distancing and creating other opportunities for infection. If a patient is permitted to bring a child with them to the health care center, and compelled to do so for lack of childcare, that child also faces unnecessary exposure risks, and increases the risk to health care center staff as well.

110. Once patients arrive at the health care center, there will often be additional exposure risks. Patients may be unable to maintain complete social distancing with other patients or health care staff, even before they reach the location where they will receive their pill, particularly at entrances and in common areas of the facility. In many cases, patients will have to touch doors, elevators, and/or other surfaces within the hospital, clinic, or medical office. To obtain the mifepristone pill and provide the incidental signature on paperwork required by the REMS,

[48] Rachel K. Jones, Elizabeth Witwer, & Jenna Jerman, *Abortion Incidence and Service Availability in the United States, 2017*, Guttmacher Inst., at 7 (Sept. 2019), https://www.guttmacher.org/report/abortion-incidence-service-availability-us-2017.

patients will likely need to have close contact with at least one health care professional. Even though health care professionals are very well-versed in infection control, these encounters still necessarily carry some risk. While abortion and miscarriage care are essential services to which patients must retain access during the pandemic, Defendants make accessing such care needlessly risky.

111. This travel and social contact necessitated by the Requirement is directly contrary to guidance issued by the CDC within Defendant HHS. For instance, the CDC advises people to stay at home and avoid any travel, including local travel, specifically cautioning that bus or train travel, or gas or rest stops during car travel, will expose individuals to infection risk.[49] The CDC emphasizes that children, like adults, should maintain social distancing and not have close contact with those outside the immediate household.[50] For groceries and other purchases, the CDC stresses that individuals should "[o]rder food and other items online for home delivery or curbside pickup (if possible). Only visit the grocery store, or other stores selling household essentials, in person when you absolutely need to."[51]

112. The CDC specifically advises patients to limit visits to pick up medications, and to use mail-order or delivery services, if possible, for all of their prescriptions.[52]

113. For the significant majority (75%) of people seeking abortions who are poor or low-

---

[49] *Coronavirus Disease 2019 (COVID-19): Travel, Coronavirus in the United States -- Considerations for Travelers*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/coronavirus/2019-ncov/travelers/travel-in-the-us.html (last updated May 22, 2020).

[50] *Coronavirus Disease 2019 (COVID-19): Daily Life & Coping, Help Stop the Spread of COVID-19 in Children Outbreak*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/children/protect-children.html (last updated May 20, 2020).

[51] CDC, *Running Essential Errands*, *supra* note 26.

[52] *Id.*

income, such travel and associated expenses will also often lead to delays that may, in turn, increase medical risk. Research has long shown that the costs and logistics associated with having to travel for an abortion delays patients' access to care.

114. During the COVID-19 pandemic and associated unemployment crisis, low-income patients are particularly likely to struggle to pay for and arrange travel. Already as of late April, 43% of U.S. adults reported that they or someone in their household had lost a job or taken a cut in pay due to the pandemic, and among lower-income adults, 52% said they or someone in their household has experienced direct impact on their take-home pay.[53] In April, more than half (53%) of lower-income adults said they would have trouble paying some of their bills that month.[54]

115. Moreover, COVID-19 has upended many of the networks and resources on which people would typically rely in arranging transportation and childcare. Many schools and day care centers are closed. Because of social distancing guidelines, many people are not seeing family members, friends, and neighbors to whom they might normally turn for childcare assistance or to borrow a car or get a ride.

116. Many patients suffering from intimate partner violence face additional challenges in accessing abortion care, even under normal circumstances. Abusers often sabotage their partners' efforts to avoid pregnancy; isolate them from their networks of friends and family; and deprive them of money, access to transportation, and access to health care. COVID-19, the associated economic fallout, and self-isolation and social distancing guidelines in response to the pandemic, all threaten to exacerbate these obstacles and burdens.

---

[53] Kim Parker, Juliana Menasce Horowitz, & Anna Brown, *About Half of Lower-Income Americans Report Household Job or Wage Loss Due to COVID-19*, Pew Research Ctr. (Apr. 21, 2020), https://www.pewsocialtrends.org/2020/04/21/about-half-of-lower-income-americans-report-household-job-or-wage-loss-due-to-covid-19/.

[54] *Id.*

117. Because the Requirement substantially increases the costs, risks, and logistical challenges of accessing abortion care during the COVID-19 pandemic, some patients will be delayed to the point when they cannot obtain a medication abortion at all, and will instead have to undertake the greater exposure risks associated with an in-office procedural abortion.

118. Indeed, patients who have been exposed to SARS-CoV-2 or are exhibiting any symptoms of COVID-19 may have no choice but to delay their abortion by 14 days, or until they can obtain a negative test, based on the facility's quarantine policy. The Requirement denies such patients the option to receive care promptly without ever having to leave their homes.

119. The needless medical risks imposed by the Mifepristone In-Person Dispensing Requirement during COVID-19 are particularly dangerous for people with lower incomes and people of color, who comprise a disproportionate share of impacted patients and generally have fewer resources at their disposal to mitigate the risks of COVID-19. People of color are significantly more likely to suffer severe illness and fatality from COVID-19.

120. Because of the nature of SARS-CoV-2 transmission, the harm that the Mifepristone In-Person Dispensing Requirement imposes has repercussions far beyond the patients themselves. This is particularly true for low-income people, people of color, and immigrants, who are more likely to work in essential jobs, where they will continue to have contact with other members of the community, and more likely to live in intergenerational or multi-family housing where introducing the virus puts others, including elderly family members, at severe risk.

121. The Requirement jeopardizes the safety of Plaintiffs, Plaintiffs' members, their patients, their staff, and the public at large with no countervailing benefit.

CLAIMS FOR RELIEF

COUNT I
(Substantive Due Process)

122. The allegations of paragraphs 1 through 121 are incorporated as though fully set forth herein.

123. The FDA's *de facto* denial of requests to suspend the Mifepristone In-Person Dispensing Requirement during the COVID-19 pandemic violates patients' right to privacy and liberty as guaranteed by the due process clause of the Fifth Amendment of the U.S. Constitution by imposing life-threatening viral exposure risks as a condition of accessing abortion care while serving no government interest, thereby imposing an undue burden on patients' right to abortion.

COUNT II
(Equal Protection)

124. The allegations of paragraphs 1 through 121 are incorporated as though fully set forth herein.

125. Defendants' *de facto* denial of requests to suspend the Mifepristone In-Person Dispensing Requirement during the COVID-19 pandemic violates Plaintiffs' members' and their patients' right to equal protection of the laws under the Fifth Amendment to the U.S. Constitution by treating mifepristone prescribers and their patients differently from other similarly situated clinicians and patients and imposing a unique barrier to provision of mifepristone without any rational government interest justifying that discriminatory treatment.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask for the following relief:

126. Declare, pursuant to 28 U.S.C. § 2201, that the application of the Mifepristone In-Person Dispensing Requirement during the COVID-19 pandemic violates the Fifth Amendment of the United States Constitution;

127. Issue preliminary and permanent injunctive relief, without bond, restraining the enforcement, operation, and execution of the Mifepristone In-Person Dispensing Requirement for the duration of the COVID-19 pandemic, by enjoining Defendants, their agents, employees, appointees, or successors, from enforcing, threatening to enforce, or otherwise applying the following "Elements to Assure Safe Use" ("ETASU") and components thereof, of the mifepristone REMS, for the duration of the COVID-19 pandemic and until such time as Defendants demonstrate that medically unnecessary travel to a health care facility no longer poses a significant threat of SARS-CoV-2 transmission and illness associated with COVID-19:

- ETASU C (Restricted Dispensing), providing that mifepristone may be dispensed only in a hospital, clinic, or medical office and not by mail or through a pharmacy;
- ETASU D (Patient Form), **only** to the extent it (1) requires patients obtaining mifepristone to sign the form in the physical presence of the prescriber, rather than signing remotely through technology or giving oral consent that the prescriber documents in the patient's record; and (2) requires the prescriber to present the patient with a copy of the form at the hospital, clinic, or office, rather than promptly providing a copy of the form electronically or by mail; and
- ETASU A (Prescriber Certification), **only** to the extent it requires clinicians seeking to prescribe mifepristone to attest that they will (1) obtain the patient's physical signature on the Patient Agreement Form, rather than obtaining the patient's signature remotely through technology or documenting the patient's oral consent in the patient's record; (2) present the patient with a copy of the form at the hospital, clinic, or office, rather than promptly providing a copy of the form electronically or by mail; (3) place in the patient's medical record a copy of the form containing

the patient's physical signature, rather than placing a copy of the form signed remotely through technology or documenting the patient's oral consent in the patient's record; (4) record the serial number of the mifepristone package in the patient's record in cases where the patient obtains the mifepristone through a pharmacy; and (5) comply with any reporting requirements by reference to the serial number from the mifepristone package in cases where the patient obtains the mifepristone through a pharmacy.

128. Award to Plaintiffs costs, expenses, and attorneys' fees pursuant to 28 U.S.C. § 2412; and

129. Award such other, further, and different relief as the Court deems just and proper.

Dated: May 27, 2020

Respectfully submitted,

/s/ John A. Freedman

AMERICAN CIVIL LIBERTIES UNION FOUNDATION
Julia Kaye*
Anjali Dalal*
Ruth Harlow*
Rachel Reeves*
Jennifer Dalven*
125 Broad Street, 18th Floor
New York, NY 10004
(212) 549-2633
(212) 549-2650 (fax)
jkaye@aclu.org
adalal@aclu.org
rharlow@aclu.org
rreeves@aclu.org
jdalven@aclu.org

Lorie Chaiten*
1640 North Sedgwick Street
Chicago, IL 60614-5714
rfp_lc@aclu.org

ARNOLD & PORTER KAYE SCHOLER LLP
John A. Freedman (D. Md Bar. No 20276)
R. Stanton Jones (D. Md. Bar No. 20690)
David J. Weiner*
Jocelyn A. Wiesner*
Andrew Tutt*
Gina Colarusso*
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com
stanton.jones@arnoldporter.com
david.weiner@arnoldporter.com
jocelyn.wiesner@arnoldporter.com
andrew.tutt@arnoldporter.com
gina.colarusso@arnoldporter.com

Pro hac vice application forthcoming

Counsel for Plaintiffs American College of Obstetricians and Gynecologists, Council of University Chairs of Obstetrics and Gynecology, New York State Academy of Family Physicians, Honor MacNaughton, M.D., and SisterSong Women of Color Reproductive Justice Collective

CERTIFICATE OF SERVICE

I hereby certify that this document will be served on the Defendants in accordance with Fed. R. Civ. P. 4.

/s/ John A. Freedman

John A. Freedman
601 Massachusetts Ave., NW
Washington, D.C., 20001
T: (202) 942-5000
john.freedman@arnoldporter.com

Exhibit J

Society of Family Planning & SFP RESEARCH FUND

August 13, 2021

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Urology, Obstetrics, and Gynecology
5901-B Ammendale Road
Beltsville, MD 20705-1266

Re: US Food and Drug Administration's review of the risk evaluation and mitigation strategy for mifepristone

Dear Dr. Christine Nguyen:

On May 7, 2021, the US Food and Drug Administration (FDA) announced a review of the risk evaluation and mitigation strategy for the drug mifepristone (hereafter, the mifepristone REMS). On behalf of the Society of Family Planning, the academic society for Complex Family Planning subspecialists and over 1,000 academicians, scientists, and partners focused on abortion and contraception research and clinical care, we write to share relevant evidence to support your review of the mifepristone REMS. We appreciate the opportunity to lend the expertise of the Society and its members to this process and applaud your efforts, as a science-based agency, to center sound medical evidence in the decision-making process related to mifepristone and its distribution and use.

As the organization representing Complex Family Planning Fellowship-trained obstetrician-gynecologists—the leaders in clinical care and medical education related to complex abortion and contraception—we conclude the additional controls provided by the REMS are not medically necessary to ensure patient safety. Our 30 years of experience within the Fellowship providing abortion and pregnancy loss care in complex cases, as well as the existing evidence on this topic described in detail below, does not support requiring provider certification and registration to prescribe mifepristone or restricting the healthcare professionals that can prescribe mifepristone. Mifepristone is extremely safe and highly effective when provided via a health center, pharmacy, or home delivery, and does not require a clinician to oversee dispensing.

On behalf of our expert membership, we offer the following summary of peer-reviewed scientific evidence related to the mifepristone REMS, with a focus on research published since the most recent FDA-approved labeling change in 2016. **We conclude that the current REMS, specifically the provisions that require provider certification and registration and restrict where mifepristone may be dispensed, confers no benefit in terms of safety, efficacy, or acceptability of the drug mifepristone and instead creates barriers to use that negatively impact public health and equity in access to care.**

Requiring provider certification and registration to prescribe mifepristone is unnecessary because it does not increase patient safety and constrains abortion provision.

- **The mifepristone REMS currently requires that providers are specially certified to prescribe the drug and must register as prescribers directly with the manufacturer(s); however, there is no evidence this requirement increases abortion safety**. 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 <1% across multiple studies of mifepristone use for early abortion.[1–3]

- **Requiring provider certification and registration prevents many providers from incorporating mifepristone into their scope of practice**. In a representative national population-based survey of obstetrician-gynecologists, Grossman and colleagues found that 28% of obstetrician-gynecologists who did not currently provide care using mifepristone would do so if they could prescribe it similarly to other drugs.[4] Several recent, rigorous qualitative studies with diverse groups of clinicians have also demonstrated how the REMS creates barriers to incorporation of mifepristone into practice by creating administrative burdens that clinical champions are unable to overcome.[5,6]

The current restrictions on where mifepristone may be dispensed are unnecessary because mifepristone dispensing in clinical care settings is not associated with higher efficacy, greater safety, or greater acceptability compared to dispensing in brick-and-mortar pharmacies or via postal mail or delivery service.

- **The requirement for in-person dispensing of mifepristone in certain health care settings confers no safety benefit**. Through the mifepristone labeling change approved in 2016, the FDA recognized that requiring misoprostol be administered in clinical settings as part of early abortion care is unnecessary. As the summary of the peer-reviewed literature below suggests, patient self-administration of mifepristone at home is effective, safe, and acceptable. However, the current mifepristone REMS further require that mifepristone be distributed “only in…clinics, medical offices, and hospitals.”

- **Mifepristone can be safely dispensed in brick-and-mortar pharmacies**. Pharmacists are well qualified to assure safe dispensing of medications with a comparable safety profile to the 200 mg mifepristone tablet, including the 300 mg formulation of mifepristone for Cushing’s syndrome, which is not subject to a REMS. Evidence from high-income countries with health care infrastructure comparable to the US has demonstrated the acceptability of pharmacy dispensing of mifepristone. For example, mifepristone is currently distributed by pharmacists in Canada, a practice that Canadian physicians report facilitates the provision of medication abortion with mifepristone.[7] In the

US, physicians support pharmacy dispensing of mifepristone. In a qualitative study of primary care providers' perceptions of and experiences with mifepristone, Rasmussen and colleagues found that primary care providers in Illinois support pharmacy dispensing of mifepristone, describing it as a more patient-centered approach to administration of this drug.[8] Further, a recent US study demonstrated that pharmacy dispensing of mifepristone is safe and effective. In a study that included eight pharmacies in California and Washington state, Grossman and colleagues demonstrated that mifepristone dispensing by pharmacists in the pharmacy setting after the patient received counseling from a clinician is as effective (93.5% abortion completion with medication alone) as in-clinic dispensing efficacy reported by Winikoff and colleagues in a large multi-site national trial.[9,10] In Grossman and colleagues' study, only three (1.3%) participants visited an emergency department during the study follow up period, a lower proportion than most clinical trials of medication abortion using in-clinic mifepristone administration (range 2.9-4.1%).[10,11]

- **Mifepristone can also be safely dispensed by mail**. In a large (N=1,157 abortions) national US-based clinical trial of mifepristone dispensing by mail (the Teleabortion study), Chong and colleagues also 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 an adverse event rate of 0.65% in a large (N=233,805 medication abortions) retrospective cohort study of in-clinic mifepristone administration.[12,13]

- **Retrospective analyses of rapid practice adaptations in the context of the COVID-19 pandemic further demonstrate the safety, efficacy, and acceptability of mifepristone dispensing by mail**. In a large (N=52,218) retrospective cohort study, Aiken and colleagues 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.[14] 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 for home administration. Investigators found that while medication abortion was equally effective in the telemedicine model (98.8%) vs the traditional in-clinic mifepristone administration model (98.2%, p=1.0), individuals using telemedicine had a shorter wait time between first contact and initiating the medication abortion (6.5 days vs. 10.7 days, p<0.001).

- **Whether patients receive mifepristone at a pharmacy or by mail, they report high acceptability**. In their pharmacy dispensing study, Grossman and colleagues report that 74.3% of patients would recommend pharmacy dispensing of mifepristone to a friend in a similar situation, and 65.4% were highly satisfied with their abortion experience.[9] Hyland and colleagues report that 97% of women cared for by an Australian telemedicine medication abortion service report high satisfaction, and Chong and colleagues report that 85% of participants in the Teleabortion study found their abortion experience "very satisfactory".[12,15]

Requiring provider certification and registration to prescribe mifepristone and mifepristone dispensing restrictions may lead to abortions happening later in pregnancy. Unfortunately, abortions become more socially and clinically complicated the further along in a pregnancy the abortion occurs.[2,16–18] Thus, restrictions such as the mifepristone REMS that limit people's ability to access abortion as soon as they discover they are pregnant negatively impact public health. Delays are particularly problematic for people with low incomes as abortions after the first trimester are more expensive and often result in even further delays in obtaining a desired abortion.[19–21] In Canada, where abortions are covered as part of universal health care, the proportion of abortions in the second trimester decreased by approximately 12% after mifepristone deregulation.[1] In the US, where limited access and cost are major contributors to delays in abortion, lifting the REMS may result in an even greater shift in abortions to earlier gestational ages.

The National Academies of Science, Engineering, and Medicine defines quality abortion care as safe, effective, patient-centered, timely, efficient, and equitable.[16] **By unnecessarily limiting the number of mifepristone providers in the US, the mifepristone REMS adversely impacts timeliness and equity in access to care.** As the academic society representing Complex Family Planning subspecialists, scientists, and partners focused on abortion and contraception research and clinical care, we hope this sound medical evidence is held central in your review of the mifepristone REMS. We appreciate your commitment to centering science and ensuring that policy decisions are based on the latest evidence.

Sincerely,

The Society of Family Planning Board of Directors

References:

1. Schummers L, Darling E, Gavowsky A, et al. Do medication abortion complications increase when mifepristone is available without regulations restricting practice? A population-based study using linked health administrative data from Canada. *BMJ Sex Reprod Heal*. 2021;47(e1). 10.1136/bmjsrh-2020-bsacp.4.
2. Upadhyay UD, Desai S, Zlidar V, et al. Incidence of emergency department visits and complications after abortion. *Obstet Gynecol*. 2015;125(1):175-183. doi:10.1097/AOG.0000000000000603
3. Kapp N, Lohr PA. Modern methods to induce abortion: Safety, efficacy and choice. *Best Pract Res Clin Obstet Gynaecol*. 2020;63:37-44. doi:10.1016/j.bpobgyn.2019.11.008
4. Grossman D, Grindlay K, Altshuler AL, Schulkin J. Induced abortion provision among a national sample of obstetrician-gynecologists. *Obstet Gynecol*. 2019;133(3):477-483. doi:10.1097/AOG.0000000000003110
5. Srinivasulu S, Yavari R, Brubaker L, Riker L, Prine L, Rubin SE. US clinicians' perspectives on how mifepristone regulations affect access to medication abortion and early pregnancy loss care in primary care. *Contraception*. 2021;104(1):92-97. doi:10.1016/j.contraception.2021.04.017
6. Calloway D, Stulberg DB, Janiak E. Mifepristone restrictions and primary care: Breaking the cycle of stigma through a learning collaborative model in the United States. *Contraception*. 2021;104(1):24-28. doi:10.1016/j.contraception.2021.04.002
7. Munro S, Guilbert E, Wagner MS, et al. Perspectives among Canadian physicians on factors influencing implementation of mifepristone medical abortion: A national qualitative study. *Ann Fam Med*. 2020;18(5):413-421. doi:10.1370/afm.2562
8. Rasmussen KN, Janiak E, Cottrill AA, Stulberg DB. Expanding access to medication abortion through pharmacy dispensing of mifepristone: Primary care perspectives from Illinois. *Contraception*. 2021;104(1):98-103. doi:10.1016/j.contraception.2021.03.022
9. Grossman D, Baba CF, Kaller S, et al. Medication abortion with pharmacist dispensing of mifepristone. *Obstet Gynecol*. 2021;137(4):613-622. doi:10.1097/AOG.0000000000004312
10. Winikoff B, Dzuba IG, Chong E, et al. Extending outpatient medical abortion services through 70 days of gestational age. *Obstet Gynecol*. 2012;120(5):1070-1076. doi:10.1097/AOG.0b013e31826c315f
11. Chen MJ, Creinin MD. Mifepristone With buccal misoprostol for medical abortion. *Obstet Gynecol*. 2015;126(1):12-21. doi:10.1097/AOG.0000000000000897
12. Chong E, Shochet T, Raymond E, et al. Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic. *Contraception*. 2021;104(1):43-48. doi:10.1016/j.contraception.2021.03.019
13. Cleland K, Creinin MD, Nucatola D, Nshom M, Trussell J. Significant adverse events and outcomes after medical abortion. *Obstet Gynecol*. 2013;121(1):166-171. doi:10.1097/AOG.0b013e3182755763
14. Aiken A, Lohr P, Lord J, Ghosh N, Starling J. Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study. *BJOG An Int J Obstet Gynaecol*. 2021;128(9):1464-1474. doi:10.1111/1471-0528.16668

15. Hyland P, Raymond EG, Chong E. A direct-to-patient telemedicine abortion service in Australia: Retrospective analysis of the first 18 months. *Aust New Zeal J Obstet Gynaecol*. 2018;58(3):335-340. doi:10.1111/ajo.12800
16. National Academies of Sciences, Engineering, and Medicine. *The Safety and Quality of Abortion Care in the United States*. National Academies Press (US); 2018. doi:10.17226/24950
17. Raymond EG, Grimes DA. The comparative safety of legal induced abortion and childbirth in the United States. *Obstet Gynecol*. 2012;119(2):215-219. doi:10.1097/AOG.0b013e31823fe923
18. Bartlett LA, Berg CJ, Shulman HB, et al. Risk factors for legal induced abortion-related mortality in the United States. *Obstet Gynecol*. 2004;103(4):729-737. doi:10.1097/01.AOG.0000116260.81570.60
19. Jones RK, Jerman J. Time to appointment and delays in accessing care among U.S. abortion patients. 2016. www.guttmacher.org. Accessed August 6, 2021.
20. Foster DG, Kimport K. Who seeks abortions at or after 20 weeks? *Perspect Sex Reprod Health*. 2013;45(4):210-218. doi:10.1363/4521013
21. Ely G, Polmanteer RSR, Caron A. Access to abortion services in Tennessee: Does distance traveled and geographic location influence return for a second appointment as required by the mandatory waiting period policy? *Heal Soc Work*. 2019;44(1):13-21. doi:10.1093/hsw/hly039

Exhibit K

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

October 6, 2021

Janet Woodcock, MD
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: U.S. Food and Drug Administration's review of the risk evaluation and mitigation strategy for mifepristone

Dear Acting Commissioner Woodcock:

On behalf of the American College of Obstetricians and Gynecologists (ACOG), representing more than 60,000 physicians and partners dedicated to advancing women's health, we write to express our strong support for the review of the risk evaluation and mitigation strategy (REMS) for mifepristone currently underway at the U.S. Food and Drug Administration (FDA). ACOG supports efforts to improve access to quality women's health care and, given the decades of research and data reinforcing the safety of this medication, urges the FDA to remove the REMS and Elements to Assure Safe Use (ETASU) requirements for mifepristone.

Mifepristone has been used by over 3 million women in the United States since FDA approval in 2000 and robust evidence exists regarding the safety of mifepristone for medication-induced abortion.[1,2,3,4*] The REMS and ETASU requirements for mifepristone are inconsistent with those for other medications with similar safety profiles, and create barriers to access without demonstrated improvements to patient safety or outcomes. These medically unnecessary requirements restricting access to mifepristone interfere with the ability of obstetrician–gynecologists and other health care professionals to deliver the highest quality care for their patients. In addition to being supported by researchers, clinicians, and more than twenty years of data, removing the REMS and ETASU requirements for mifepristone is consistent with FDA's mission to ensure the safety and efficacy of medications and help "…the public get the accurate and science-based information they need to use medical products…"[5]

ACOG is the premier professional membership organization for obstetrician-gynecologists and produces practice guidelines for women's health clinicians based on the best available science and evidence. As referenced in ACOG Practice Bulletin 225, *Medication Abortion Up to 70 Days of Gestation*, medication abortion is a safe and effective method of providing abortion. The REMS restrictions for mifepristone do not make care safer, are not based on medical evidence or need, and create barriers to patient access to medication abortion.[6, 7, 8] Abortion is an essential component of comprehensive health care and is a time-sensitive service for which a delay of several weeks, or in some cases days, may increase the risks or

[*] Recent evidence also supports the use of mifepristone to improve the safe and effective medical management of early pregnancy loss.
See Schreiber CA, Creinin MD, Atrio J, Sonalkar S, Ratcliffe SJ, Barnhart KT. Mifepristone pretreatment for the medical management of early pregnancy loss. N Engl J Med 2018;378:2161-70. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa1715726. Retrieved July 9, 2018; and
Westhoff CL. A Better medical regimen for the management of miscarriage. N Engl J Med 2018;378:2232-3. Available at: https://www.nejm.org/doi/full/10.1056/NEJMe1803491. Retrieved July 9, 2018.

potentially make it completely inaccessible.[9] Furthermore, research conducted during the COVID-19 pandemic, when enforcement of the in-person dispensing requirement for mifepristone was suspended, demonstrates the safety of providing abortion through telehealth contact and mailed medications.[10,11] Additionally, recent data suggests that patients offered telemedicine with mailed medications had abortions earlier than those without this option.[12] Removing the REMS and ETASU on mifepristone will improve access to medication-induced abortion and enhance patient care.

ACOG is pleased that the FDA is conducting a thorough review of the REMS restrictions for mifepristone and urges the FDA to remove the medically unnecessary REMS and ETASU restrictions that hinder access to medication abortion. Thank you for your attention to this critical issue. We are available to answer any questions.

Sincerely,

Maureen G. Phipps, MD, MPH, FACOG
Chief Executive Officer
American College of Obstetricians and Gynecologists

---

[1] Improving Access to Mifepristone for Reproductive Health Indications. Position Statement. American College of Obstetricians and Gynecologists. June 2018. Available at https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications.
[2] Cleland K, Smith N. Aligning mifepristone regulation with evidence: Driving policy change using 15 years of excellent safety data. *Contraception*. 2015;92(3):179-181. doi:10.1016/j.contraception.2015.06.016.
[3] Sixteen Years of Overregulation: Time to Unburden Mifeprex. *N Engl J Med*. 2017;376(8):790-794.
[4] Song LP, Tang SY, Li CL, Zhou LJGYK, Mo XT. Early medical abortion with self-administered low-dose mifepristone in combination with misoprostol. *J Obstet Gynaecol Res*. 2018;44(9):1705-1711. doi:10.1111/jog.13716.
[5] U.S. Food and Drug Administration. FDA Mission. Available at https://www.fda.gov/about-fda/what-we-do. Retrieved September 20, 2021.
[6] Medication abortion up to 70 days of gestation. ACOG Practice Bulletin No. 225. American College of Obstetricians and Gynecologists. Obstet Gynecol 2020;136:e31–47.
[7] Grossman D, Grindlay K, Altshuler AL, Schulkin J. Induced abortion provision among a national sample of obstetrician-gynecologists. Obstet Gynecol 2019;133:477–83.Raymond EG, Blanchard K, Blumenthal PD, Cleland
[8] Raymond EG, Blanchard K, Blumenthal PD, Cleland K, Foster AM, Gold M, et al. Sixteen years of overregulation: time to unburden mifeprex. Mifeprex REMS Study Group. N Engl J Med 2017;376:790–4.
[9] Joint Statement on Abortion Access During the COVID-19 Outbreak. March 18, 2020. Available at https://www.acog.org/news/news-releases/2020/03/joint-statement-on-abortion-access-during-the-covid-19-outbreak.
[10] Chong E, Shochet T, Raymond E, Platais I, Anger H, Raidoo S, et al. Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic. Contraception 2021.
[11] Kerestes C, Murayama S, Tyson J, Natavio M, Seamon E, Raidoo S, et al. Provision of medication abortion in Hawai‘i during COVID-19: Practical experience with multiple care delivery models. Contraception 2021.
[12] Aiken A, Lohr P, Lord J, Ghosh N, Starling J. Effectiveness, safety and acceptability of no-test medical abortion provided via telemedicine. British J Obstet Gynecol 2021.

Exhibit L

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

AMA
AMERICAN MEDICAL ASSOCIATION

June 21, 2022

Robert Califf, MD
Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: U.S. Food and Drug Administration actions related to mifepristone

Dear Dr. Califf:

On behalf of the American College of Obstetricians and Gynecologists (ACOG), representing more than 60,000 physicians and partners dedicated to advancing women's health and individuals seeking obstetric and gynecologic care, and the American Medical Association, we write to express our appreciation for the support demonstrated by the U.S. Food and Drug Administration (FDA) in response to the needs of individuals seeking reproductive care. Respectfully, we request that additional actions are taken to improve access to quality women's health care. In anticipation of the crisis to abortion access that is expected to follow the United States Supreme Court's decision in the *Dobbs v. Jackson Women's Health Organization* case, we strongly urge you to prioritize the following evidence-based decisions that will increase access to mifepristone:

- Reconsider the implementation of the Risk Evaluation and Mitigation Strategies (REMS) and Elements to Assure Safe Use (ETASU) requirements for mifepristone and ensure the process does not add unnecessary and unmitigated burdens for physicians, patients, and pharmacies; and
- Explicitly preempt state laws relating to mifepristone that are not evidence-based, that interfere with the medically necessary and appropriate use of a safe and effective drug, and that frustrate the FDA's regulatory decisions relating to mifepristone, and that have inconsistent policies and laws restricting access to mifepristone.

Mifepristone is Safe and Effective

Mifepristone is a safe, effective, and important component of treatment and management for early pregnancy loss (i.e., spontaneous abortion, miscarriage, missed abortion) and induced abortion. Mifepristone has been used by over 3 million women in the United States since FDA approval in 2000, and robust evidence exists regarding the safety of mifepristone for medication-induced abortion.[1,2,3,4]

Early pregnancy loss is common, occurring in 10% of all clinically recognized pregnancies and affects approximately 1 million women in the U.S. annually.[5,6] Recent evidence demonstrates that mifepristone significantly improves the safe and effective medical management of early pregnancy loss when taken as part of a two-medication regimen.[7,8] A 2018 randomized controlled trial demonstrated that people who received mifepristone in addition to misoprostol experienced increased rates of complete expulsion and required fewer procedures compared to those who received misoprostol alone.[9] Therefore, we ask that the FDA modify the mifepristone label indicating that mifepristone is approved for the use of miscarriage management.

As referenced in ACOG clinical guidance, the evidence supports medication abortion as a safe and effective method of providing abortion care.[10] Barriers to accessing mifepristone do not make care safer, are not based on medical evidence, and create barriers to patient access to essential reproductive health care.[11, 12] Abortion care is time-sensitive: delays in care increase risk to patients and potentially results in an abortion being completely inaccessible.[13] Research conducted during the COVID-19 pandemic demonstrates that when enforcement of the in-person dispensing requirement for mifepristone was suspended, abortion through telehealth contact and mailed medications was safe.[14]

According to reaffirmed ACOG guidance, second-trimester abortion is safely accomplished through medical induction or medical abortion, especially when compared with other methods.[15] Mifepristone followed in 24–48 hours by misoprostol is the most effective regimen for second-trimester medical abortion.[16] In fact, that regimen is up to 91% successful within 24 hours of initiation of misoprostol, and outcomes include a significantly shorter induction interval and fewer adverse effects than misoprostol alone.[17]

FDA Preemption of State Laws that Restrict Access to Mifepristone

There are currently nineteen states that require a physician to be present upon delivery of mifepristone; two states have made it illegal to use mifepristone at earlier gestation ages than the label allows.[18] Neither of these state restrictions are evidence-based.

Mifepristone is approved by the FDA to be used with misoprostol for medication abortion through 70 days of gestation.[19,20] In 2016, the FDA expanded the gestational age limit from 49 to 70 days (10 weeks) to better correspond with recently published evidence.[21,22] The 2015 systematic review reported average effectiveness rates of 96.7% in the 8th week, 95.2% in the 9th week, and 93.1% in the 10th week. Subsequently, evidence-based guidelines concluded that mifepristone followed in 24–48 hours by misoprostol is the most effective regimen for second-

trimester medical abortion.[23] Currently, strong evidence supports the use of the mifepristone regimen through 77 days gestation, and multi-center study published in 2022 found that many physicians offer mifepristone up to 77 days.[24,25]

Experts, including ACOG, and the growing body of scientific evidence, demonstrate that the FDA regulations should preempt those state laws and prevent state lawmakers from imposing restrictions that are not evidence-based, that interfere with the medically necessary and appropriate use of a safe and effective drug, that frustrate access to necessary care and are inconsistent with the FDA's regulatory decisions relating to mifepristone.

Revisit or Remove the Risk Evaluation and Mitigation Strategies (REMS) and Elements to Assure Safe Use (ETASU) Requirements for Mifepristone

Recognizing the accomplishments of the FDA in modifying the REMS for mifepristone, we continue to urge the FDA to remove or make further changes to the REMS and ETASU requirements to allow obstetrician–gynecologists and other physicians to deliver the highest quality care for their patients. While the FDA updated the REMS for mifepristone in December 2021, the REMS for mifepristone still requires use of a provider agreement form, a patient agreement form and dispensing from a pharmacy certified by the drug distributors. The agency and manufacturers have not yet defined the pharmacy certification process; however, we are concerned that this unnecessary hurdle could serve as a deterrent to pharmacies' decisions to stock and dispense mifepristone. To increase access to mifepristone, we ask that, at a minimum, the FDA simplify the pharmacy certification process, eliminate the requirement for patients to sign a form to get the drug, lift the requirement that prescribers acquire a certification from the manufacturer, and evaluate adding protections for availability of mifepristone via telehealth.

Failure to Improve Access to Mifepristone Will Threaten to Exacerbate the Maternal Mortality Crisis

The United States leads the developed world in rates of maternal mortality. In 2020, the most recent year for which data is available, there were 23.8 deaths per 100,000 live births, up from 20.1 in 2019.[26] Alarmingly, the maternal mortality rate for Black women was 55.3 deaths per 100,000 live births, 2.9 times the rate for White women, and rates significantly increased for both Black and Hispanic women.[27] The rising maternal mortality rates and persistent racial disparities in maternal outcomes are unacceptable. However, without sufficient access to abortion care, including mifepristone, these figures are certain to climb.

Current data support an association between restricted access to safe and legal abortion and higher rates of maternal morbidity and mortality, with already vulnerable populations experiencing the greatest burden.[28,29,30] At just 0.3 deaths per 100,000 abortions performed at or before 8 weeks, the mortality rate associated with abortion is significantly lower than the mortality rate associated with childbirth.[31] A lack of access to mifepristone will result in more pregnancies, including high-risk pregnancies, which is associated with the much higher maternal mortality rates described above. A recent study estimated a total, nationwide abortion ban would increase pregnancy-related deaths by 7% in the first year and 21% in subsequent years, including a 33% increase for Black people.[32]

Furthermore, research suggests that a lack of abortion access carries the risk of adverse physical outcomes. The harm of mifepristone restrictions is also more pronounced for patients with medical conditions for which a medication abortion may be preferable to uterine aspiration. Such examples include uterine fibroids that significantly distort the cervical canal or uterine cavity, congenital uterine anomalies, or introital scarring related to infibulation.[33] Patients with asthma are candidates for medication abortion because misoprostol does not cause bronchoconstriction and actually acts as a weak bronchodilator.[34] Carrying a pregnancy to term is also associated with mental health conditions. A 2017 study found women who were denied abortions experienced more symptoms of anxiety, lower self-esteem, and lower life satisfaction after one week than their counterparts who obtained abortions.[35] Perinatal depression, which includes major and minor depressive episodes that occur during pregnancy or in the first 12 months after delivery, is one of the most common medical complications during pregnancy and the postpartum period, affecting one in seven.[36] Finally, restrictions on the use of telemedicine have a disproportionate effect on rural people's access to abortion, who are forced to travel substantially greater distances outside of their communities than nonrural women for care.[37]

Thank you for your attention to this critical issue and your continued partnership with us. Your commitment and dedication to advancing women's health and individuals receiving obstetric and gynecologic care is recognized and appreciated. Should you have any questions, please contact Rebecca Lauer, Manager, Federal Affairs, at rlauer@acog.org.

Sincerely,

Maureen G. Phipps, MD

Maureen G. Phipps, MD, MPH, FACOG
Chief Executive Officer
American College of Obstetricians and Gynecologists

James L. Madara, MD
CEO, Executive Vice President
American Medical Association

cc: The Honorable Joseph R. Biden, Jr.
The Honorable Kamala D. Harris

[1] Improving Access to Mifepristone for Reproductive Health Indications. Position Statement. American College of Obstetricians and Gynecologists. June 2018. Available at https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications.
[2] Cleland K, Smith N. Aligning mifepristone regulation with evidence: Driving policy change using 15 years of excellent safety data. *Contraception*. 2015;92(3):179-181. doi:10.1016/j.contraception.2015.06.016.
[3] Sixteen Years of Overregulation: Time to Unburden Mifeprex. *N Engl J Med*. 2017;376(8):790-794.
[4] Song LP, Tang SY, Li CL, Zhou LJGYK, Mo XT. Early medical abortion with self-administered low-dose mifepristone in combination with misoprostol. *J Obstet Gynaecol Res*. 2018;44(9):1705-1711. doi:10.1111/jog.13716.
[5] Early pregnancy loss. Practice Bulletin No. 150. American College of Obstetricians and Gynecologists. Obstet Gynecol 2015;125:1258-67.
[6] Ventura SJ, Curtin SC, Abma JC, Henshaw SK. Estimated pregnancy rates and rates of pregnancy outcomes for the United States, 1990-2008. Natl Vital Stat Rep 2012;60(7):1-21.
[7] Schreiber CA, Creinin MD, Atrio J, Sonalkar S, Ratcliffe SJ, Barnhart KT. Mifepristone pretreatment for the medical management of early pregnancy loss. N Engl J Med 2018;378:2161-70.
[8] Westhoff CL. A Better medical regimen for the management of miscarriage. N Engl J Med 2018;378:2232-3.
[9] Schreiber CA , Creinin MD , Atrio J , Sonalkar S , Ratcliffe SJ , Barnhart KT . Mifepristone pretreatment for the medical management of early pregnancy loss . N Engl J Med 2018; 378:2161-70.
[10] Medication abortion up to 70 days of gestation. ACOG Practice Bulletin No. 225. American College of Obstetricians and Gynecologists. Obstet Gynecol 2020;136:e31–47.
[11] Grossman D, Grindlay K, Altshuler AL, Schulkin J. Induced abortion provision among a national sample of obstetrician-gynecologists. Obstet Gynecol 2019;133:477–83.
[12] Raymond EG, Blanchard K, Blumenthal PD, Cleland K, Foster AM, Gold M, et al. Sixteen years of overregulation: time to unburden mifeprex. Mifeprex REMS Study Group. N Engl J Med 2017;376:790–4.
[13] Joint Statement on Abortion Access During the COVID-19 Outbreak. March 18, 2020. Available at: https://www.acog.org/news/news-releases/2020/03/joint-statement-on-abortion-access-during-the-covid-19-outbreak.
[14] Kerestes C, Murayama S, Tyson J, Natavio M, Seamon E, Raidoo S, et al. Provision of medication abortion in Hawai‘i during COVID-19: Practical experience with multiple care delivery models. Contraception 2021.
[15] Second-trimester abortion. Practice Bulletin No. 135. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121:1394–1406.
[16] Ibid.
[17] Ibid.
[18]Guttmacher Institute. Medication Abortion. Available at: https://www.guttmacher.org/state-policy/explore/medication-abortion. Retrieved June 16, 2022.
[19] Second-trimester abortion. Practice Bulletin No. 135. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121:1394–406.
[20] World Health Organization. Medical management of abortion . Geneva: WHO; 2018. Available at: https://apps.who.int/iris/bitstream/handle/10665/278968/9789241550406-eng.pdf?ua=1. Retrieved June 16, 2022.
[21]Abbas D, Chong E, Raymond EG. Outpatient medical abortion is safe and effective through 70 days gestation. Contraception 2015;92:197–9.
[22] Chen MJ, Creinin MD. Mifepristone with buccal misoprostol for medical abortion: a systematic review. Obstet Gynecol 2015;126:12–21.
[23] Second-trimester abortion. Practice Bulletin No. 135. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121:1394–406.
[24] 3. Dzuba IG, Chong E, Hannum C, et al. A non-inferiority study of outpatient mifepristone-misoprostol medical abortion at 64-70 days and 71-77 days of gestation. Contraception. 2020;101(5):302-308.
[25] Upadhyay UD, Raymond EG, Koenig LR, et al. Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study. JAMA Intern Med. 2022;182(5):482–491.
[26] Hoyert DL. Maternal mortality rates in the United States, 2020. National Center for Health Statistics Health E-Stats. February 23, 2022. doi: https://dx.doi.org/10.15620/cdc:113967
[27] Ibid.
[28] Addante, A.N., et al., *The association between state-level abortion restrictions and maternal mortality in the United States, 1995-2017.* Contraception, 2021. 104(5): p. 496-501.

[29] Hawkins, S.S., et al., *Impact of State-Level Changes on Maternal Mortality: A Population-Based, Quasi-Experimental Study.* Am J Prev Med, 2020. 58(2): p. 165-174.
[3030] Verma, N. and S.A. Shainker, *Maternal mortality, abortion access, and optimizing care in an increasingly restrictive United States: A review of the current climate.* Semin Perinatol, 2020. 44(5): p. 151269.
[31] Medicaid Coverage of Abortion. Guttmacher Institute. Medicaid Coverage of Abortion. Available at: https://www.guttmacher.org/evidence-you-can-use/medicaid-coverage-abortion. Retrieved June 16, 2022.
[32] Stevenson, AJ. The Pregnancy-Related Mortality Impact of a Total Abortion Ban in the United States: A Research Note on Increased Deaths Due to Remaining Pregnant. *Demography*. December 1, 2021; 58 (6):2019–2028. doi: https://doi.org/10.1215/00703370-9585908.
[33] Second-trimester abortion. Practice Bulletin No. 135. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121:1394–406.
[34] Ibid.
[35] Biggs MA, Upadhyay UD, McCulloch CE, Foster DG. Women's Mental Health and Well-being 5 Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort Study. *JAMA Psychiatry.* 2017;74(2):169–178. https://doi:10.1001/jamapsychiatry.2016.3478.
[36] Gavin NI, Gaynes BN, Lohr KN, Meltzer-Brody S, Gartlehner G, Swinson T. Perinatal depression: a systematic review of prevalence and incidence. *Obstet Gynecol*. 2005;106:1071–83.
[37] Health disparities in rural women. Committee Opinion No. 586. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;123:384–8.

Exhibit M

Chronology of FDA Communications

	Date	Record citation	Brief description
1	11/3/2015	Hughes Decl. Ex. E	Letter to FDA from medical and public health researchers
2	11/4/2015	Hughes Decl. Ex. F	Letter to FDA from the American Congress of Obstetricians and Gynecologists
3	2/4/2016	ECF No. 1-9	Letter to FDA from 30 organizations, including American College of Obstetricians and Gynecologists (ACOG), Society of Family Planning (SFP), Planned Parenthood Federation of America (PPFA), and others
4	3/29/2016	ECF No. 1-10	FDA's Cross Discipline Team Leader Review
5	6/20/2019	Hughes Decl. Ex. H	Letter to FDA from American Academy of Family Physicians (AAFP)
6	3/30/2020	Hughes Decl. Ex. D	Letter to FDA and DHHS from Plaintiff States
7	5/27/2020	Hughes Decl. Ex. I	Complaint in *American College of Obstetricians and Gynecologists, et al. v. FDA, et al*, Case No. 8:20-cv-01320-TDC (D. Md.)
8	8/13/2021	Hughes Decl. Ex. J	Letter to FDA from SFP
9	9/29/2021	Hughes Decl. Exs. B (letter) and C (app'x)	Letter to FDA from Plaintiffs in *Chelius v. Becerra*, No. 1:17-cv-00493-JAO-RT (D. Haw.), with appendix
10	10/6/2021	Hughes Decl. Ex. K	Letter to FDA from ACOG
11	6/21/2022	Hughes Decl. Ex. L	Letter to FDA from American Medical Association (AMA) and ACOG
12	10/4/2022	Hughes Decl. Ex. A	Citizen Petition from ACOG and 48 other organizations, including AAFP, AMA, PPFA, SFP, and others