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

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[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"

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[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.

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[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.

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[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]

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[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]

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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-

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[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.

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[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

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**Pro hac vice* application forthcoming

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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

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