Exhibit 4

March 27, 2020

BY ELECTRONIC MAIL

Janet Woodcock, M.D., Director
Center for Drug Evaluation and Research
United States Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
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Re: Request Regarding COVID-19

Dear Dr. Woodcock,

We are health care practitioners who provide reproductive health services, including abortion care, to patients across the country. As you know, COVID-19, a novel coronavirus, has spread to more than 100 locations internationally, including the United States. We are deeply concerned about protecting our patients' access to high-quality, timely abortion care, and reducing community spread of COVID-19, during this unprecedented emergency. As the American College of Obstetrics and Gynecologists recently emphasized, "[a]bortion is an essential component of comprehensive health care" and a "time-sensitive" service for which delay can cause harm.[1]

The federal government, including the U.S. Food and Drug Administration ("FDA"), has already taken substantial action to ensure that essential health services remain available during this national emergency, while still taking measures to limit community spread of the virus.[2] For instance, demonstrating its "ability to pivot and adapt as the situation warrants in light of a public

[1] Am. Coll. of Obstetricians & Gynecologists, Am. Board of Obstetrics & Gynecology, Am. Ass'n of Gynecologic Laparoscopists, Am. Gynecological & Obstetrical Soc'y, Am. Soc'y for Reprod. Med., Soc'y for Acad. Specialists in Gen. Obstetrics & Gynecology, Soc'y of Fam. Plan., and Soc'y for Maternal-Fetal Med., *Joint Statement on Abortion Access During the COVID-19 Outbreak* (Mar. 18, 2020), https://www.acog.org/news/news-releases/2020/03/joint-statement-on-abortion-access-during-the-covid-19-outbreak; *see also* Am. Coll. of Obstetricians & Gynecologists, Am. Ass'n of Gynecologic Laparoscopists, Am. Soc'y for Reprod. Med., Am. Urogynecologic Soc'y, Soc'y of Fam. Plan., Soc'y of Gynecologic Surgeons, Soc'y for Maternal-Fetal Med., and Soc'y of Gynecologic Oncology, *Joint Statement on Elective Surgeries* (Mar. 16, 2020), https://www.acog.org/news/news-releases/2020/03/joint-statement-on-elective-surgeries (pregnancy-related procedures for which delay will negatively affect patient health and safety should not be delayed).

[2] *See e.g.*, 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), https://www.fda.gov/media/136317/download [hereinafter "FDA Policy for Certain REMS Requirements"]; U.S. Food & Drug Admin., *FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic: Guidance for Industry, Investigators, and Institutional Review Boards* (Mar. 2020), https://www.fda.gov/media/136238/download; U.S. Drug Enforcement Admin, *COVID-19 Information Page*, https://www.deadiversion.usdoj.gov/coronavirus.html (last visited Mar. 18, 2020) (expanding ability of practitioners to issue prescriptions for controlled substances during the public health emergency).

health emergency,"[3] FDA recently published guidance indicating that it "does not intend to take enforcement action against [drug] sponsors or others for accommodations made regarding laboratory testing or imaging study requirements" imposed pursuant to a Risk Evaluation and Mitigation Strategy ("REMS") during the Public Health Emergency declared by the Secretary of Health and Human Services on January 31, 2020, "provided that such accommodations were made based on the judgment of a health care professional."[4] In addition, the Centers for Medicare and Medicaid Services ("CMS") have announced a temporary expansion of Medicare telehealth benefits.[5] CMS explained that it "is imperative during this public health emergency that patients avoid travel, when possible, to physicians' offices, clinics, hospitals, or other health care facilities where they could risk their own or others' exposure to further illness."[6]

Given the unprecedented threat to public health posed by COVID-19, and in accordance with guidance from the World Health Organization and the Centers for Disease Control and Prevention, as well as the enforcement discretion FDA is already exercising with regard to certain REMS elements, we write to request that FDA temporarily lift a regulatory requirement that impedes medication abortion providers' efforts to minimize the spread of COVID-19 while continuing to safely provide essential health care to our patients. Specifically, we are requesting that FDA exercise enforcement discretion with regard to one element to assure safe use ("ETASU") of the shared REMS program for Mifeprex® and its generic, mifepristone (collectively, "mifepristone"): ETASU C, which requires that mifepristone be dispensed only in clinics, medical offices, and hospitals.

We respectfully ask FDA to announce that, because of the public health emergency posed by COVID-19, it does not intend to take action if certified health care providers—in compliance with all other elements of the mifepristone REMS, all other federal and state laws, and the standard of care—dispense mifepristone (for use in a regimen with misoprostol) to eligible patients by mail rather than in-person at a clinic, medical office, or hospital. We request that FDA continue this limited exercise of enforcement discretion until the Secretary of Health and Human Services declares the end of the Public Health Emergency.[7]

This action is critical given the importance of social distancing and other strategies recommended to reduce the risk of COVID-19 transmission, since it will prevent vulnerable individuals from unnecessarily entering a health care facility when their needs can be safely met

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[3] U.S. Food & Drug Admin., *Coronavirus (COVID-19) Update: FDA Provides More Regulatory Relief During Outbreak, Continues to Help Expedite Availability of Diagnostics* (Mar. 16, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help.

[4] FDA Policy for Certain REMS Requirements, *supra* n.2, at 7.

[5] Ctrs. for Medicare & Medicaid Servs., *Medicare Telemedicine Health Care Provider Fact Sheet* (Mar. 17, 2020), https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet?inf_contact_key=255903cd45b988193a87d7bff084d88f; Ctrs. for Medicare & Medicaid Servs., *Medicare Telehealth Frequently Asked Questions (FAQs)* (Mar. 17, 2020), https://edit.cms.gov/files/document/medicare-telehealth-frequently-asked-questions-faqs-31720.pdf?inf_contact_key=d318f0e018efa2f8cca55f7b65733f08.

[6] Ctrs. for Medicare & Medicaid Servs., *Medicare Telehealth Frequently Asked Questions (FAQs)* (Mar. 17, 2020), https://edit.cms.gov/files/document/medicare-telehealth-frequently-asked-questions-faqs-31720.pdf?inf_contact_key=d318f0e018efa2f8cca55f7b65733f08.

[7] Alex M. Azar II, Sec. of Health & Human Servs., *Determination that a Public Health Emergency Exists* (Jan. 31, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

remotely. It will also serve to protect health care workers and staff at abortion facilities by minimizing the risk of exposure. In addition, it is consistent with the statutory directive to ensure that any ETASU not unduly burden patient access or the health care delivery system.[8]

The proposed accommodation would allow abortion providers (where state laws allow) to reduce the risk of community spread of COVID-19 through the use of telemedicine. The President and the Secretary of Health and Human Services have both acknowledged that telemedicine is safe, effective, and a critical risk-mitigation tool in this public health emergency.[9] As health care practitioners who provide abortion services to patients across the country, including through the safe use of telemedicine, we know from both evidence and experience that medication abortion is as safe when provided via telemedicine as it is through an in-person consultation. A recent comprehensive report on the safety of abortion by the independent, nonpartisan National Academies of Sciences, Engineering, and Medicine found that "[t]here is no evidence that the dispensing or taking of [medication abortion pills] requires the physical presence of a clinician."[10] An international team of researchers conducted a systematic review of evidence concerning telemedicine for medication abortion in 2019 and found that clinical outcomes for telemedicine were similar to those reported for in-person medication abortion.[11] Over the past decade, the use of telemedicine for medication abortion has significantly expanded the availability of safe, high-quality abortion care in numerous states.

Under our proposed accommodation, the telemedicine model would work as follows: the certified prescriber would review the relevant medical information and assess patient eligibility, ordering ultrasound imaging if necessary in their best medical judgment, or relying on other appropriate diagnostic measures in accordance with the standard of care. If, after receiving comprehensive counseling, the patient is eligible for and desires a medication abortion, the provider would mail the medication to the patient. This telemedicine model would have the *identical* safeguards as the REMS—except that the patient no longer would have to visit a clinic, medical office, or hospital solely for the purpose of obtaining the mifepristone in-person. We also underscore that, like all of the care we provide, this model would be rooted in informed consent and patient self-determination.

In addition to reducing the spread of COVID-19, our proposed accommodation will reduce other barriers to care that the virus is exacerbating—particularly for people with low incomes, people of color, young people, and people living in rural areas. As businesses and schools shutter across the nation, likely for weeks or months, many of our patients are facing severe loss of income as well as enhanced childcare obligations that will delay—or altogether block—their ability to travel for abortion care. While abortion is extremely safe, the risks increase when care is unnecessarily delayed. Moreover, if patients must travel to pick up the mifepristone in person at a clinic, medical office, or hospital rather than receiving it by prescription in the mail, some will be

[8] 21 U.S.C. § 355-1(f)(2).
[9] U.S. Dep't of Health & Human Servs., *Secretary Azar Announces Historic Expansion of Telehealth Access to Combat COVID-19* (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.
[10] *See* Nat'l Acads. of Sci., Eng'g & Med., *The Safety & Quality of Abortion Care in the United States* 79 (The National Academies Press, 2018).
[11] Margit Endler et al., *Telemedicine for Medical Abortion: A Systematic Review,* 2019 Brit. J. Obstetrics & Gynecology 1094, 1098 (2019).

delayed past the point when medication abortion is available, necessitating a more invasive in-clinic procedure or potentially making it impossible for them to obtain an abortion at all.

Evidence-based research confirms that our requested accommodation is safe and effective. As you know, FDA has approved the use of mifepristone in a regimen with misoprostol to end an early pregnancy up to 10 weeks (or 70 days) of pregnancy, as measured from the first day of the woman's last menstrual period. According to FDA, this medication abortion regimen "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."[12] Indeed, since FDA approved Mifeprex for marketing in the United States in 2000, more than four million patients have used this safe, effective medication.[13] FDA has stated that "[m]ajor adverse events" are "exceedingly rare, generally far below 0.1% for any individual adverse event."[14]

Significantly, while ETASU C requires patients to pick up the mifepristone in a medical facility, FDA *already* allows patients to swallow the mifepristone at home: based on studies documenting the safety and efficacy of home administration of both mifepristone and misoprostol, FDA modified the Mifeprex labeling in 2016 to eliminate the instruction that patients take the medications at a provider's office.[15] Likewise, under our proposal, eligible patients would take the medications at home after receiving comprehensive counseling and with appropriate follow-up from a certified health care prescriber. In other words, the exercise of enforcement discretion that we propose would not change where patients may *take* the mifepristone—only whether the certified prescriber dispenses the medication to their patient by hand or by envelope.

We applaud the efforts FDA has already made to ensure that REMS program requirements do not facilitate the spread of COVID-19, and implore FDA to take—at the very least—this additional, exceedingly narrow, step to reduce the burdens and risks faced by patients seeking essential reproductive health care during this crisis.

We recognize that FDA is overwhelmed at the moment by the demands of responding to this public health crisis, and we thank you for all that you are already doing to safeguard the nation's health. But we underscore the exigency of this request. Every day, patients are turning to us for abortion care, a profoundly time-sensitive service. Any delay in this requested accommodation carries severe consequences for the health and lives of our patients and staff.

Please do not hesitate to contact us with any questions concerning this urgent request.

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[12] Ctr. for Drug Evaluation & Res., Application Number 020687Orig1s020: Mifeprex Med. Review(s) 12 (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf [hereinafter "Mifeprex 2016 Medical Review"].

[13] Danco Laboratories, LLC, *Mifeprex Effectiveness & Advantages*, https://www.earlyoptionpill.com/is-mifeprex-right-for-me/effectiveness-advantages/ (last visited Mar. 19, 2020).

[14] Mifeprex 2016 Medical Review, *supra* n.12, at 47.

[15] *See id.* at 39, 61-62.

Sincerely,

Affiliated Medical Services
Wisconsin

All Women's Health
Washington

Carafem
Georgia, Illinois, Maryland, Tennessee

Chico Feminist Women's Health Center dba Women's Health Specialists
California

Health Quarters
Massachusetts

Hope Clinic for Women, Ltd.
Illinois

Maine Family Planning
Maine

The Women's Centers
Connecticut, Georgia, New Jersey, Pennsylvania

Whole Woman's Health/Whole Woman's Health Alliance
Indiana, Maryland, Minneapolis, Texas, Virginia

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