Exhibit 4

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *et al.*, Plaintiffs, vs. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	CIV. NO. **DECLARATION OF ANGELA YINGCHE CHEN, M.D., M.P.H., FACOG, IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

Angela Yingche Chen, M.D., M.P.H., FACOG, declares and states as follows:

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

2. I am a board-certified Obstetrician-Gynecologist ("Ob-Gyn") with a specialty in family planning. I am currently a Health Sciences Associate Clinical Professor in the Department of Obstetrics and Gynecology at David Geffen School of Medicine at the University of California, Los Angeles ("UCLA"). From 2013-2017, I also served as the Medical Director of the Ryan Residency Training Program in Contraception & Abortion at the UCLA Center for Reproductive Services.

3. I am a member and Fellow of the American College of Obstetricians and Gynecologists ("ACOG"), which is the premier professional membership organization for obstetrician-gynecologists and allied professionals in the United States.

4. In 1997, I was awarded combined degrees from Boston University: B.A in Medical Science from the College of Liberal Arts; M.P.H. in Health Services, from the School of Public Health; and M.D. from the School of Medicine. I completed my Residency in Obstetrics and Gynecology at Boston Medical Center in 2001. I completed Fellowships in Clinical Research Training and Family Planning Clinical Care in 2003 at Boston University School of Medicine. I also completed a Fellowship in Medical Education at David Geffen School of Medicine at UCLA in 2013.

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

6. During the COVID-19 crisis, in order to reduce the risk of transmitting the virus, my colleagues and I have expanded our use of telehealth to safely diagnose and treat many of our patients' obstetric and gynecological needs. However, because of a Food and Drug Administration ("FDA") restriction that only permits Mifeprex® (and its generic equivalent, mifepristone) to be dispensed in clinics, medical offices, or hospitals ("In-Person Dispensing Requirement"), I cannot prescribe mifepristone to patients seeking medication abortion or medical management of miscarriage without also requiring them to travel to my office, in person, to pick up their medication. This medically unnecessary requirement threatens my patients' health and lives, as well as the health and lives of those of us who care for them, by increasing the risk of viral transmission.

My Practice and Patients and the Impact of COVID-19

7. I treat patients in a faculty Ob-Gyn practice affiliated with the Department of Obstetrics and Gynecology at the UCLA Medical Center, and at an outpatient clinic where I supervise and train Ob-Gyn residents. I have a general Ob-Gyn practice with a specialty in family planning. I offer the full scope of obstetric and gynecological care to patients of reproductive age who are seeking to become pregnant as well as those who are attempting to avoid pregnancy. I treat patients facing unintended pregnancy, providing them the full range of options, including medication and procedural abortion care. I regularly diagnose and treat a range of gynecological conditions using medications or surgery, and I treat patients who need care relating to menopause. I often see patients who have been referred to me because they have complicated medical needs that are best addressed in the tertiary care setting in which I practice. My patients come from the greater Los Angeles area and beyond, from a diverse array of communities, backgrounds, and socio-economic situations.

8. Since the onset of the COVD-19 pandemic, my colleagues and I have expanded our use of telehealth to maximize care for our patients while attempting to minimize the risk of viral exposure for them as well as for our staff. This is consistent with policies instituted by public officials throughout the country, including here in California, as well as the guidance of the medical community. For example, the Governor of California has recognized that "it is imperative to reduce the spread of COVID-19 and protect health care workers, including through the use of telehealth services, where possible, for any reason," and therefore has waived or modified the application of various laws that would impede the ability to provide care through telehealth.[1] Telehealth care allows us to evaluate and diagnose many of our patients' medical

[1] *See* Governor Gavin Newsom, *Executive Order N-43-20* (Apr. 3, 2020), https://www.gov.ca.gov/wp-content/uploads/2020/04/4.3.20-EO-N-43-20-text.pdf.

issues without the need for an in-person visit. Telehealth patients give oral consent to the provision of care via telehealth, and we record their consent in their medical record. If prescription medication is required for treatment, we can call in a prescription to the patient's local pharmacy or a mail-order pharmacy. Because of our ability to treat via telehealth, patients do not have to risk viral exposure while traveling to an in-person appointment or spend time in the medical center where they might infect or be infected by others whose needs require them to be there in person.

9. Getting to my office poses a real problem for many of my patients, particularly during the COVID-19 crisis. Some of my patients do not have access to a car and normally use public transportation to get to my office. Using public transportation significantly increases their risk of exposure; however, these patients have few other options. Some may have a friend who is able to drive them, or be able to afford a round-trip cab, uber, or other ride share service – but even those who can utilize those options, face elevated risk from being in a car with other people for the significant time it can take to get to my office. Patients who drive to my office also have to park, which involves taking a ticket from a ticket machine and paying with a credit card on the way out. They have to walk from the parking lot, take elevators, and open doors – all the while risking personal encounters with others and potential exposure from touching surfaces.

10. In addition, even under normal circumstances, my patients with children struggle to find someone to care for their children while they come to an in-person appointment. Those challenges are heightened now, as many schools and day care centers are closed because of the COVID-19 crisis. In addition to the serious hurdles of finding any childcare during the COVID-19 crisis, our patients now also have the added fear – and very real risk – that bringing someone outside the family into their home to care for their child, or sending their child to someone else's

home, will expose them and their family to a potentially deadly virus. Indeed, precisely because of those risks of viral transmission, my practice does not permit our patients to bring children or others with them into our medical facility.

11. My low-income patients who are still working during the COVID-19 crisis are also often afraid to ask for time off from work to come to an appointment for fear of losing a much-needed job, and are concerned about losing the wages their families so desperately need.

12. Fortunately, telehealth mitigates all of these concerns for many patients by reducing the need for travel and childcare and affording greater scheduling flexibility, including off-hours telehealth visits.

13. I am able to provide care entirely by telehealth for a wide array of medical needs. For instance, I regularly use telehealth to diagnose, treat, and counsel patients regarding urinary tract infections, vaginitis, rashes, and contraception needs. I perform new patient consultations and evaluations by telehealth and can even use telehealth to examine a patient's sutures and evaluate how well the patient is healing after surgery. However, many of my patients seeking medication abortion, and miscarriage care for which I prescribe mifepristone, must travel in person to my office, solely because of FDA's Mifepristone In-Person Dispensing Requirement, and thereby suffer the burdens and risks that my patients who can obtain care entirely via telehealth are able to avoid.

Treatment for Medication Abortion

14. When patients in early pregnancy contact my office seeking abortion care, my staff schedules them for a telehealth visit with me. I begin each telehealth visit by reviewing the patient's medical history and symptoms and determining the kinds of abortion for which they are eligible, including whether they require additional in-person assessment to determine their

eligibility for medication abortion. I then discuss with my patient the risks, benefits and alternatives for each kind of abortion care for which they are eligible and answer any questions they may have to ensure that they have the information they need to make an informed decision about their care. If they are eligible for, and choose, a medication abortion via telehealth, we proceed with the telehealth visit for such care. Over the past two months, my practice has treated several dozen patients who were eligible for medication abortion prescription through telehealth.

15. During the telehealth visit, I discuss the medication abortion process and review the FDA's Patient Agreement Form with the patient. After answering any questions, I ask whether they consent to a medication abortion, and if they do, I confirm that consent in their medical record. I then go over again the instructions for how and when to take their medication, what the follow-up process is, what they should do if they experience any of the (very rare) serious complications associated with mifepristone, and answer any questions they may have.

16. We then schedule the patient for an appointment to come to my office to pick up their medication in accordance with the In-Person Dispensing Requirement. During that appointment, to comply with the In-Person Dispensing Requirement, the patient signs the Patient Agreement Form that we previously reviewed during our telehealth visit. We give one copy of that form to the patient and place another in the patient's record.

17. As with the medication abortion itself, the follow-up process for the vast majority of patients is done remotely, using telephone or audio-video communications and an at-home pregnancy test. Thus, for many of my medication abortion patients, the *only* reason they have to make a trip in person to my office is because the In-Person Dispensing Requirement mandates that they do so. This requirement serves no medical purpose, but puts my patients, their families, and those of us who care for them at risk for COVID-19.

18. A recent patient experience places this in sharp relief. One of my patients, whom I have treated for years for prenatal care, childbirth, and ongoing gynecological needs, contacted my office seeking a medication abortion. I was able to conduct the assessment and counseling for medication abortion entirely via telehealth, but she still had to travel to my office to pick up the mifepristone because of the In-Person Dispensing Requirement. Unfortunately, she struggled to find someone who could care for her baby while she made the trip. Although my colleagues and I would have been delighted to see her baby, we could not permit her to bring her child because of the risk of COVID-19. The people she otherwise might have hired or asked for assistance with childcare were staying home because of the COVID-19 crisis. Her efforts to find childcare delayed her ability to pick up her medication. In the end, she made the difficult decision to ask her elderly mother to come to her home to take care of her baby. That required her mother to travel away from her own home and then back again; not only was my patient put at unnecessary risk of viral exposure, but her elderly mother was as well. Had I been able to mail her the medication or write a prescription for its delivery to her home, she could have received care sooner and avoided unnecessary risk of exposure for her, her mother, and the health care professionals who treated her.

Medical Management of Early Pregnancy Loss (Miscarriage)

19. The In-Person Dispensing Requirement also imposes risks and burdens on my patients who are suffering from early pregnancy loss. Mifepristone in combination with misoprostol is often the most appropriate way to medically manage a miscarriage. Telehealth offers the opportunity to mitigate the risk of viral exposure and additional burdens for some patients seeking (and health care staff providing) miscarriage treatment, but the In-Person

Dispensing Requirement prevents my patients and those of us who care for them from taking full advantage of the benefits of telehealth.

20. During nights and weekends, pregnant patients who experience pain, spotting, bleeding, or other concerns often seek treatment at the UCLA Emergency Department. The UCLA Emergency Department does a complete evaluation of pregnant patients who present with symptoms of possible early pregnancy loss, including lab work and ultrasound. If they diagnose a miscarriage, where medically appropriate, they discharge the patient with instructions to seek follow-up care with their Ob-Gyn. My own patients, as well as some who are referred from the Emergency Department, contact me for follow-up care.

21. During the COVID-19 crisis, I can review the records from the Emergency Department and counsel the patient via telehealth about their options for treatment. But for the In-Person Dispensing Requirement, for those patients who choose medical management of their miscarriage, I could provide their medication (mifepristone and misoprostol) by mail or calling in a prescription to a mail-order pharmacy.

22. These patients are often scared and do not wish to come back to a medical facility after spending hours in the Emergency Department. They face all of the same risks and burdens as my patients who are forced to make an unnecessary trip to my office for medication abortion: the travel, childcare, and time away from work – and woven into all of those logistics and costs, is now the unnecessary risk of exposing themselves and their families to a deadly virus.

23. I cared for a pregnant patient recently who had a gestational sac that was not growing properly. We had been monitoring the situation on a weekly basis when she began to suffer cramping and bleeding. I knew she was suffering early pregnancy loss and could have cared for her entirely via telehealth if not for the In-Person Dispensing Requirement. Instead, she

had to travel to my clinic for treatment I could otherwise have provided her in the privacy of her own home, creating additional exposure risk for her, her family, as well as for me and my staff.

24. This issue also arises for patients who receive Ob-Gyn care at UCLA's satellite clinics that do not employ a certified mifepristone provider. I often see patients whose miscarriages have been diagnosed through lab work and ultrasound at a satellite clinic, but who then must travel to my clinic at the main UCLA medical center just to pick up their medication. I have treated patients who, while miscarrying, have had to travel 20-30 miles each way just to pick up medication. If not for the In-Person Dispensing Requirement, I could review these patients' charts, comprehensively counsel them via telehealth, and then mail the mifepristone to them directly or call in a prescription to a pharmacy.

25. It is possible to treat patients suffering from early pregnancy loss with misoprostol alone, which (unlike mifepristone) I am allowed to prescribe through a local pharmacy; however, research demonstrates that mifepristone and misoprostol together are a more effective treatment than misoprostol alone. A patient whose miscarriage is managed with misoprostol only, rather than mifepristone and misoprostol together, is more likely to need a follow-up in-clinic procedure to fully evacuate the uterine contents, which will require another in-person visit and additional risk of viral exposure because of person-to-person contact. Unfortunately, the In-Person Dispensing Requirement stands as an obstacle to the safest and most effective treatment for many patients.

26. The medically unnecessary In-Person Dispensing Requirement deprives my patients seeking medication abortion and those suffering early pregnancy loss of safe and appropriate care via telehealth, placing their health and lives, and the health and lives of those who care for them, at risk.

I declare under penalty of perjury that the foregoing is true and correct. Executed on May 21, 2020.

Angela Yingche Chen, M.D., M.P.H., FACOG