

Exhibit 5

**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 SERINA E. FLOYD,
M.D., M.S.P.H., FACOG, IN SUPPORT
OF PLAINTIFFS' MOTION FOR
PRELIMINARY INJUNCTION**

Serina E. Floyd, M.D., M.S.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 the Vice President of Medical Affairs/Medical Director of Planned Parenthood of Metropolitan Washington, D.C., Inc. ("PPMW"), a non-profit corporation dedicated to providing high quality primary and reproductive health care to patients from Washington, D.C., northern Virginia, and parts of Maryland. As PPMW's Medical Director, I direct and oversee all health care services PPMW offers. I am also an Assistant Professor of Medical Education at the University of Virginia and Vice-Chair of the Planned Parenthood National Medical Committee.

3. I am a board-certified Obstetrician-Gynecologist ("Ob-Gyn") and a member and Fellow of the American College of Obstetricians and Gynecologists ("ACOG") – the premier

professional membership organization for obstetrician-gynecologists and allied professionals in the United States. I serve as the Vice-Chair of ACOG's Committee on Health Care for Underserved Women.

4. I am a member of SisterSong Women of Color Reproductive Justice Collective ("SisterSong"), a nationwide membership organization dedicated to strengthening and amplifying the collective voices of indigenous women and women of color to achieve reproductive justice.

5. I received my undergraduate degree from Emory University in 1996 and, in 2000, received a Master of Science in Public Health, with a focus on Maternal and Child Health, at the University of North Carolina at Chapel Hill. I received my medical degree from University of North Carolina at Chapel Hill in 2001 and completed my residency in Obstetrics and Gynecology at Duke University Medical Center in 2005.

6. I submit this declaration in support of Plaintiffs' Motion for a Preliminary Injunction. During the COVID-19 crisis, I and my colleagues at PPMW have expanded our use of telehealth to diagnose and treat an array of medical issues in order to limit the risk of exposure to COVID-19 for our patients and staff. However, because of the Food and Drug Administration ("FDA") restriction that requires patients to obtain mifepristone only in person at a hospital, clinic, or medical office, we cannot prescribe mifepristone to patients seeking medication abortion or medical management of a miscarriage without requiring them to travel to our health center to pick up their medication (the "In-Person Dispensing Requirement"). This unnecessary requirement threatens our patients' health and lives, as well as the health and lives of the PPMW staff who treat them, by increasing the risk of exposure to the virus that causes COVID-19.

7. It is particularly dangerous, unjustified, and cruel to subject our patients, who are predominantly people of color, to needless viral exposure risks as a condition of obtaining abortion or miscarriage care when these patients are among the very populations that are already suffering severe illness and disproportionate fatality rates from COVID-19.

My Patients and Practice

8. I oversee clinical practice and directly provide care at all three of PPMW's health centers: one in Gaithersburg, Maryland, one in Suitland, Maryland, and one in the District of Columbia. Our health centers offer a broad range of health care, including, among others things: primary care, contraception counseling and provision, diagnosis and treatment of gynecologic disorders, testing and treatment for sexually transmitted infections, PrEP and PEP for HIV, gender affirming hormone therapy, cancer screenings, behavioral health, miscarriage treatment, and abortion.

9. The majority of our patients have lower incomes and, as noted above, are people of color. Our health centers are the primary source of family planning and reproductive health care for many of our patients.

COVID-19 and Telehealth

10. In March of this year, Maryland Governor Hogan and District of Columbia Mayor Bowser each declared a state of emergency to prevent the spread of SARS-CoV-2, the novel virus that causes COVID-19.¹ Like public officials across the country, they ordered non-essential

¹ Governor Lawrence J. Hogan, Jr., *Declaration of State of Emergency and Existence of Catastrophic Health Emergency – COVID-19* (Mar. 5, 2020), <https://governor.maryland.gov/wp-content/uploads/2020/03/Proclamation-COVID-19.pdf>; Mayor Muriel Bowser, *Mayor's Order 2020-045: Declaration of Public Emergency: Coronavirus (COVID-19)* (Mar. 11, 2020), https://mayor.dc.gov/sites/default/files/dc/sites/mayormb/release_content/attachments/MO.DeclarationofPublicEmergency03.11.20.pdf.

businesses to close, required social distancing, and issued stay-at-home orders.² In addition, recognizing the need to protect the public against viral transmission and to preserve essential health care resources, each implemented new policies to expand access to telehealth and to encourage its use among health care providers and patients as a critical measure in the fight against COVID-19.³ Even as our communities slowly begin to reopen, public health and elected officials have made clear that public distancing, remote work, and limiting person-to-person contact – including through the use of telehealth – will continue to play a critical role in our ability to protect against broad and fatal transmission of this novel coronavirus.⁴

11. PPMW has dramatically expanded its use of telehealth in response to the COVID-19 crisis. To maximize our use of telehealth where appropriate, and to assure that the more limited number of in-person appointments we still offer are available without undue delay for patients who require them, we screen all patients in advance of their appointments to determine their eligibility for telehealth. Even for patients who need in-person care, we attempt to provide as much of their care remotely as we can. For example, we do intakes and take medical history

² Governor Lawrence J. Hogan, Jr., *Governor's Order No. 20-03-30-01, Amending and Restating the Order of March 23, 2020, Prohibiting Large Gatherings and Events and Closing Senior Centers, and All Non-Essential Businesses and Other Establishments, and Additionally Requiring All Persons to Stay at Home* (Mar. 30, 2020), <https://governor.maryland.gov/wp-content/uploads/2020/03/Gatherings-FOURTH-AMENDED-3.30.20.pdf>; Mayor Muriel Bowser, *Mayor's Order 2020-054: Stay at Home Order* (Mar. 30, 2020), <https://mayor.dc.gov/release/mayor-bowser-issues-stay-home-order>.

³ DC HEALTH, *Guidance on Use of Telehealth in the District of Columbia* (Mar. 12, 2020), https://dchealth.dc.gov/sites/default/files/dc/sites/doh/page_content/attachments/Memo%20-%20Guidance%20on%20the%20Use%20of%20Telehealth.pdf; Governor Lawrence J. Hogan, Jr., *Governor's Order No. 20-04-01-01, Amending and Restating Order No. 20-03-20-01 to Further Authorize Additional Telehealth Services* (Apr. 1, 2020), <https://governor.maryland.gov/wp-content/uploads/2020/04/Telehealth-Amended-4.1.20.pdf>.

⁴ See Quint Forgey, *Mayor Bowser says D.C. could begin reopening next week*, Politico (May 21, 2020), <https://www.politico.com/news/2020/05/21/washington-dc-reopen-date-muriel-bowser-273330>; REOPEN DC ADVISORY GRP., *ReOpen DC: Recommendations to the Mayor* (May 21, 2020), https://coronavirus.dc.gov/sites/default/files/dc/sites/coronavirus/page_content/attachments/%23ReOpen%20DC%20Advisory%20Group%20Recommendations%20to%20Mayor%20Bowser.pdf.

via telehealth. In that way, our patients are physically present in our health centers for only the minimal amount of time necessary to obtain the care they need. Our expanded telehealth services are essential to our ability to meet our patients' medical needs while limiting patient presence in our health centers and protecting our patients against unnecessary risk of viral exposure associated with traveling in person to an appointment.

12. Many of our patients, particularly those who live in the District of Columbia, use public transportation to travel to in-person appointments. Others have to ask friends or family to drive them, or borrow a car. Still others have to pay acquaintances or a ride-share service. In each case, they are subjected to an increased risk of COVID-19. By obtaining care via telehealth, they avoid that risk, as well as the costs and challenges associated with finding transportation to their appointment.

13. Many of our patients have children at home whose schools and day care centers are closed because of the high risks associated with person-to-person contact during the pandemic. For the same reason – the risk of viral transmission – we do not permit patients to bring children or others with them into our health centers. Utilizing telehealth means these patients can receive the medical consultation and treatment they need without having to find someone to care for their children and risk viral exposure for themselves and their families.

14. In addition, telehealth permits patients not feeling well enough to travel – sick patients, suffering from COVID-19 symptoms – to remain home and still obtain care. It goes without saying that keeping such patients (as well asymptomatic patients who can still spread the virus) isolated at home is essential to protecting our health center staff, other patients, and our communities as a whole.

15. We offer care via telehealth to patients seeking a wide array of medical services, including among others: contraception counseling and care; pregnancy options counseling and other pregnancy-related services as appropriate; diagnosis and treatment of certain gynecological conditions, dermatological conditions, sexually transmitted infections, urinary tract infections, and upper respiratory infections; PrEP and PEP for HIV; diagnosis and treatment of anxiety and depression as well as other mental health care; gender affirming hormone therapy; and management of diabetes.

16. We also offer care via telehealth to patients seeking medication abortion and miscarriage care. Both treatments involve a combination of two FDA-approved prescription medications – mifepristone and misoprostol. But, as detailed below, the FDA’s In-Person Dispensing Requirement for mifepristone prevents us from realizing telehealth’s full potential to avoid needless exposure risks for this subset of patients, because all patients using mifepristone must still travel in person to our health center, even when there is no clinical reason for them to do so.

Medication Abortion Care

17. During the pandemic, where possible and medically appropriate, we conduct our medication abortion visits via telehealth. During the telehealth call, we obtain the information necessary to determine whether the patient is eligible for a medication abortion through telehealth alone or whether an in-person assessment or testing is indicated before we can make an eligibility determination. This includes a discussion of the patient’s medical history, symptoms, and health circumstances. We also discuss the risks, benefits, and alternatives to medication abortion, review the information contained in the FDA’s Patient Agreement Form

and Medication Guide for Mifeprex® (which generally contain the same information), and answer any questions the patient may have.

18. If the patient is eligible and chooses to proceed with a medication abortion, they either come inside the clinic, or in some instances we are able to meet them at their car to deliver their medication. In either case, they then sign the Patient Agreement Form and consent documents, and we provide instructions for how and when to take their medication and follow-up. There is simply no clinical reason why any of this has to happen in person, except that the In-Person Dispensing Requirement mandates it. If not for the In-Person Dispensing Requirement, eligible patients could obtain the consultation and treatment they needed entirely via telehealth and safely obtain their medication by mail.

19. Finally, I note that for the vast majority of our medication abortion patients, the follow-up process is entirely remote – using telephonic communications and at-home pregnancy testing. The In-Person Dispensing Requirement is the only reason that eligible patients have to leave their home at all for this care.

The In-Person Dispensing Requirement Harms PPMW Patients

20. The In-Person Dispensing Requirement imposes unnecessary risk of viral transmission by requiring our patients to break with social distancing and self-isolating as they travel to our health centers, interact personally with PPMW staff, address child care needs, or bring their children with them in their car – exposing them and their children to unnecessary risk. It also causes unnecessary and harmful delay in access to care. The In-Person Dispensing Requirement forces 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

21. I recently saw a patient for a medication abortion who did not have a car and had to pay someone to drive her to her appointment. The person who drove her became impatient as they waited, and decided to leave. Since that was the only ride the patient had, she left as well, and then had to find another ride, at another time, and incur additional risk of viral exposure, to come back to the clinic to pick up her medication. By the time she was able to return, she was very close to the limit when medication abortion care is available. If it had taken her just a couple more days to arrange to come in, she would no longer have been eligible for a medication abortion and would have had to have an in-clinic procedure instead, further increasing her risk of exposure. The cost, delay in treatment, and risk of viral exposure this patient experienced was completely unnecessary; if not for the In-Person Dispensing Requirement, she could have had her appointment by telehealth and received her medication promptly through the mail.

22. Another recent patient had to borrow a car to come to her appointment. She had no one to care for her three young children, so she had to bring them with her. Based on her initial intake, I determined that she did not need to come into the clinic for an in-person assessment or testing – which was fortunate, since we do not permit patients to bring children or others in with them during the COVID-19 crisis. However, my patient and her children were all put at risk of viral exposure as they made a medically unnecessary trip to our health center in a borrowed car. If not for the In-Person Dispensing Requirement, this patient could have received all her care at home. She would not have needed to borrow a car and bring her children with her to her appointment, putting them and herself at risk.

23. In addition, the In-Person Dispensing Requirement subjects our patients to risk because of protestors who congregate outside our health centers and approach patients, often shouting and not wearing face masks. Indeed, we recently had an incident where protestors at our health center, who were not wearing face masks, chased multiple patients into the street as the patients tried to get away from them. In addition to the fact that these interactions can be traumatic for our patients, they elevate the risk that our patients will be exposed to a deadly virus. But for the In-Person Dispensing Requirement, many of our patients could avoid these potentially fatal interactions.

Medical Management for Early Pregnancy Loss (Miscarriage)

24. The In-Person Dispensing Requirement also harms my patients suffering from early pregnancy loss (also known as miscarriage). Patients who are miscarrying early in pregnancy have three treatment options: (1) “expectant management” (i.e., wait to see if the uterus fully expels its contents on its own); (2) a vacuum aspiration procedure, in which suction is applied to evacuate the contents of the uterus; or (3) treatment with medications, for which the superior evidence-based regimen is a combination of mifepristone and misoprostol.

25. I see pregnant patients who come to our health center for an ultrasound to document a pregnancy (i.e., after having taken a home pregnancy urine test) and learn at that time that they have suffered a pregnancy loss. Unprepared for such a diagnosis, these patients often choose expectant management. If, during follow-up, the patient reports that they have not had any bleeding or otherwise reports symptoms that suggest that expectant management has not worked, they require further treatment. Those who choose medication management could, if not for the In-Person Dispensing Requirement, receive their medication at home; however, because

of the Requirement, they have to travel in person back to our health center to pick up mifepristone to manage their miscarriage.

26. I also see patients who are miscarrying and come to the emergency department of a local hospital where I provide Ob-Gyn on-call service once every month. I cannot give these patients mifepristone in the emergency room because the hospital's emergency department is not a certified Mifeprex provider. Even if I had the medication available, some patients are not ready to make a decision about treatment while dealing with their miscarriage diagnosis and an emergency department visit. In some cases, these patients ask if they can follow up with me at PPMW at a later point for medical management of their miscarriage. While they can have their records transferred to PPMW for such treatment, because of the In-Person Dispensing Requirement, they still have to make a wholly unnecessary trip into our health center to obtain the mifepristone. But for the In-Person Dispensing Requirement, I could conduct their follow-up visit entirely by telehealth, and they could receive their medication by mail.

Conclusion

27. PPMW has gone to extensive lengths to keep our patients and staff safe while providing the health care our patients and communities need during the COVID-19 crisis. The In-Person Dispensing Requirement undermines those efforts. Were it not for this medically unnecessary requirement, our eligible medication abortion patients and our patients suffering early pregnancy loss could obtain care without the need for – and the risks and burdens associated with – an unnecessary trip outside their home to our health centers.

28. Because a majority of our patients seeking abortion and miscarriage care are people with low incomes who hail from communities of color, restrictions on these urgent reproductive health services reverberate most harmfully in these communities. While that is true

even under normal circumstances, the risks are particularly severe now, in the context of the COVID-19 pandemic, when Black and Latinx people are dying at substantially higher rates than others. It is deeply inconsistent with both my clinical judgment and my moral code to have to force my patients – solely because of the FDA’s needless restrictions – to take on heightened, and entirely unnecessary, risks of exposure to a life-threatening virus in order to obtain care.

I declare under penalty of perjury that the foregoing is true and correct. Executed on May 25, 2020.

A handwritten signature in black ink, appearing to read "Serina E. Floyd". The signature is fluid and cursive, with the first name "Serina" and last name "Floyd" clearly distinguishable.

Serina E. Floyd, M.D., M.S.P.H., FACOG