

Exhibit D

Declaration of Julie Amaon, M.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

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

vs.

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

Defendants.

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

[CIVIL RIGHTS ACTION]

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

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

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

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

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

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

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

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

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

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

Limited Access to Abortion in Rural Minnesota

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

¹ Jones RK, Witwer E and Jerman J, "Abortion Incidence and Service Availability in the United States, 2017," <https://www.guttmacher.org/report/abortion-incidence-service-availability-us-2017>.

² 2019 Minnesota Adolescent Sexual Health Report https://kstp.com/kstpImages/repository/cs/files/2019_ashr_final.pdf.

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

COVID-19 and the Expansion of Telehealth Services

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

³ Guttmacher Institute, "Induced Abortion in the United States," September, 2019, <https://www.guttmacher.org/fact-sheet/induced-abortion-united-states#>.

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

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

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

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

⁵ *Id.*; *ACOG v. FDA*, 2020 WL 8167535 (D.Md., Aug. 19, 2020).

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

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

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

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

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

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

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

Burdens and Risk for Patients Following Supreme Court Stay

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

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

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

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

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

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

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

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

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

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


Barriers to Prescribing Mifepristone

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

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

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

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



Julie Amaon, M.D.