Exhibit F

Declaration of Jane Roe, 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 [redacted], 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

[redacted], M.D., a/k/a/ Jane Roe, 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 Family Medicine doctor trained in abortion care. I live and practice in a rural area in the western United States, approximately 100 miles away from the nearest abortion clinic. I am seeking to proceed pseudonymously out of fear of being exposed—nationally and in my small, rural town—as an abortion provider. In light of the extreme harassment and violence, including murder, that has been perpetrated against abortion providers in the United States, I attempt to keep my provision of abortion care as private as possible; I am painfully aware that my primary practice does not have the safeguards in place that exist at the abortion clinics (several hours away) where I work part-time—bulletproof glass, violent intruder protocols, alarm button, separate entrance for providers, and so on. Moreover, given the significant abortion stigma in my community, I expect that I would lose many of my non-abortion patients at my primary practice if the fact of my abortion provision were widely known.

3. I am a member of Plaintiff Society of Family Planning, and I submit this declaration in support of Plaintiffs' Motion for Summary Judgment. I do so only in my individual capacity and not on behalf of any institution with which I am affiliated.

4. Attempting to comply with the Mifeprex REMS has been time-consuming, stressful, and professionally compromising. Because of the REMS, my ability to care for my patients in accordance with their needs and with my medical judgment has been conditioned on my seeking (and gaining) approval and assistance from countless individuals and committees within my health care institution. If not for the REMS, I could have simply written a prescription for Mifeprex for my patients to fill at a local or mail-order pharmacy, rather than having to mount a workplace lobbying campaign, and jeopardize my professional standing, in order to provide this safe medication onsite to my patients who need it.

5. I am a full-spectrum Family Medicine physician. In addition to my three years of residency, I completed a Family Medicine fellowship in obstetrics. I often care for three or four generations within a family—delivering a baby one day and caring for her grandmother the next. I perform a range of obstetric and gynecological services, such as cesarean sections, tubal ligations, leeps (which entails removing pre-cancerous lesions from the cervix), endometrial biopsies, and insertion and removal of intrauterine contraceptive devices.

6. I also provide miscarriage management, including by prescribing medications to evacuate the contents of a patient's uterus. When using medications to manage a miscarriage, it is the standard of care to use both Mifeprex and misoprostol, the same two drugs used in the FDA-approved medication abortion

regimen. Thus, as discussed further below, the restrictions on Mifeprex impact my ability to provide both abortion and miscarriage care.

7. I work at a hospital and affiliated clinic within a large health care system that includes multiple hospitals, each of which has one or more affiliated clinics. Many of my patients are low-income; virtually all are rural; and many travel to us from medically underserved areas in our state. Indeed, some of my patients live in areas where there are no roads—only snowmobile access in the winters.

8. Over the years, my colleagues and I have had multiple patients ask if we could provide a medication abortion, but—because we could not write them a prescription for Mifeprex to fill at a pharmacy—we had to refer all of these patients elsewhere for care. The nearest abortion clinic is a 200-mile round-trip, and some of these patients never made the journey, instead returning later for prenatal care. I recall one adolescent patient who told my colleague that she had repeatedly scheduled appointments at the abortion clinic, only to have to cancel multiple times because she simply could not make it there.

9. So, in February 2017, along with a few colleagues, I began the process of trying to get Mifeprex added to our hospital's formulary. The formulary is the list of medications approved for use by the pharmacy committees for our hospital and for our health care system, and then made available at our hospital for

dispensing or administering to patients. Based on conversations I had with colleagues about attitudes towards abortion at our institution, I concluded that there was a greater likelihood of my gaining approval to add Mifeprex to our formulary and dispense it in my office, rather than gaining approval to perform surgical abortion services in our operating room. That is because the latter would require the involvement of many clinicians, including nursing staff, certified scrub technicians, and anesthesia providers, and would thus require (at a minimum) approval from the CEO of the hospital and the departments overseeing each of those categories of clinicians, as well as the development of opt-out procedures for the supporting clinical staff.

10. Attempting to add Mifeprex to our formulary was a major undertaking. First, we had to obtain approval from the pharmacy committee at our hospital. Once that committee agreed to move forward with the process, we could elevate the request to the pharmacy committee for the entire health care system.

11. Over the next six months, we were delayed time and again in trying to get a decision from that system-level pharmacy committee—including being advised by a representative of the committee to delay raising the issue of Mifeprex until our request could undergo further "informal vetting," and then being bumped from the agenda for the committee's once-a-month meeting at least three times. In addition, the pharmacy committee representative insisted that *we* complete the

"new drug review" analysis for Mifeprex—a time-consuming assignment that, to my knowledge, is always completed by the system-level pharmacy committee, not by the hospital-level pharmacy committee or the individual physicians or pharmacists making the request. I believe this was demanded of us only because of the controversy and stigma surrounding abortion in our community, as in many places in this country.

12. Throughout the six months that we were slogging through this process—which would not have been necessary if not for the REMS—I was forced to turn away patients who needed my care. I know with certainty that, as a result, at least one of my patients was delayed past the point in pregnancy when she could obtain a medication abortion at all—which is available only up to 10 weeks of pregnancy—and had to travel 200 miles round-trip to have a surgical abortion instead. While abortion is one of the safest procedures in modern American medicine, and far safer for a woman than remaining pregnant and carrying to term, the risks associated with abortion increase as pregnancy advances. Thus, delaying a woman's abortion care increases the risks she faces.

13. It is inconsistent with both my medical judgment and my deeply held values to deny a patient's urgent request for time-sensitive medical care that I am qualified to provide—but that is exactly what the REMS required of me.

14. In September 2017, I was contacted by the Chief Medical Officer of

our health care system, who had apparently been informed of my request. To my knowledge, it is very unusual for the CMO to be involved in a formulary request, and I assume that my request was only elevated to this very high level because of the controversy surrounding abortion. He proposed a possible strategy to enable me to provide Mifeprex to my patients while avoiding the conflict that he expected would result from a system-wide debate on this question: namely, that I would prescribe and dispense Mifeprex as a "non-formulary drug," which the policy defines as "[a]n agent, which has not been reviewed by the [pharmacy committee] or has been reviewed and denied admission to the formulary."

15. This was a highly unusual application of our policy on non-formulary drugs, which to my knowledge is typically invoked in situations where patients admitted to our hospital need to continue a pre-established medication regimen for the short period of time that they are admitted. The policy on non-formulary drugs also expressly provides that usage of such medications will be "tracked and routinely reviewed . . . to evaluate appropriateness" by the system-level pharmacy committee—the very same committee that this strategy was designed to avoid, given the expectation of conflict over the abortion issue. Classifying Mifeprex as a non-formulary drug to be "tracked and routinely reviewed" meant that I had to continue to expend time, and put my professional reputation on the line, having discussions with leadership at my institution regarding my Mifeprex use. And, of

course, this designation meant that I could suddenly lose the ability to provide this care to my patients.

16. After gaining this temporary, precarious approval to stock and dispense Mifeprex on-site as a non-formulary drug, I next had to sign up with Danco (the manufacturer of Mifeprex) as a certified prescriber and set up an account with the drug distribution company. This was a significant ordeal in and of itself, further delaying my ability to care for my patients by approximately two months. I completed as much of the paperwork myself as I could, but setting up an account requires information (including on billing and shipping) that, as a doctor within a large health care institution, I do not have. This meant that I had to involve yet another colleague in the process—my Practice Administrator, who oversees finances, staffing, and other significant matters in our practice—and then repeatedly bother that person, who I know to be personally opposed to abortion, until it got done. If not for the REMS, I would not have had to compromise this important professional relationship in this manner.

17. I believe that the REMS has harmed my reputation among some of my colleagues by necessitating that I engage in an internal lobbying campaign to try to make Mifeprex available onsite, and necessitating the involvement of additional members of our staff in this care. For instance, I was informed about a senior leadership meeting at which a colleague raised as a "concern" that I was working

to make Mifeprex available at our facility (mentioning me by name).

18. *None* of this would have been necessary if I could simply write a prescription for Mifeprex for my patient to fill at a retail pharmacy, as I can do for virtually every other prescription drug. My colleagues do not have to expend such time and resources, or jeopardize their professional reputations, in order to prescribe other medications that are equally or less safe than Mifeprex.

19. Earlier in 2019, our health care system finally approved Mifeprex as a formulary drug. But this was no quick fix: ordering, stocking, and dispensing the medication remains a complicated, multi-stage process involving numerous staff members across our health care system. To begin, one provider from each individual clinic or hospital wishing to prescribe Mifeprex must register with the "buyer" for our health care system's central pharmacy. This entails attesting that they will oversee the prescription and dispensing of Mifeprex at their clinic or hospital site; completing the necessary materials for Danco; determining how many doses to order; and all of the correspondence and paperwork this necessitates. The central pharmacy then orders the medication to be stocked at the specific clinic or hospital.

20. In the Family Medicine clinic where I work, Mifeprex is stored under lock in our medication stock room, where we keep vaccines and other medications administered in the clinic (typically drugs administered by injection, or basic

painkillers like ibuprofen). When one of the medical assistants who works in my clinic sees that I have entered an order for Mifeprex, she goes into the medication stock room to obtain the pill and complete the special Mifeprex log, noting the serial number of the package (as required by the REMS) as well as the two-part patient ID (typically, the patient's medical records number and date of birth).

21. Having to comply with the REMS thus dramatically increases the number of people in our health care system who must be involved in the provision of Mifeprex. In addition to posing logistical complications, this heightens the risk of a violation of patient confidentiality—and perpetually threatens that a single individual who opposes abortion could delay or derail the process. By contrast, if not for the REMS, I could just electronically submit the prescription order to a pharmacy of my patient's choice and no one else would have to be involved.

22. Notably, formulary drugs are still subject to "annual" review by the system-level pharmacy committee (as compared to the "routine" review for non-formulary drugs)—which means that availability at our hospital is still subject to debate every year by a committee, the members of which change on a regular basis. My ability to include Mifeprex within my practice, and my patients' access to this vital care, remains precarious.

23. The Mifeprex REMS also requires me to provide my patients with and discuss, and for us each to sign, a "Patient Agreement Form" containing medical

information about Mifeprex dated to March 2016. This is not merely unnecessary from an informed consent perspective—it actively *undermines* my informed consent process by forcing me to discuss with my patients information that is inconsistent with my clinical approach and increasingly out-of-step with the research on Mifeprex as science moves forward. For instance, the form requires the patient's signature that, "[i]f my pregnancy continues after treatment with Mifeprex and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy." However, I (like many clinicians) treat the small percentage of patients whose pregnancies continue following use of the Mifeprex and misoprostol regimen with additional medication doses in the first instance, not surgery. This is well within the standard of care, yet not reflected in the form—to the contrary, the form suggests to patients that surgery is the *only* option in such a case. Moreover, the statement that "the treatment will not work . . . . in about 2 to 7 out of 100 women" is misleading and not how I counsel my patients about the expected efficacy of the treatment: while in some small number of cases, the regimen listed on the label will not fully complete the abortion, the treatment may very well still work – after, for instance, an additional dosage of misoprostol.

24. The Form is particularly ill-suited for my patients to whom I am prescribing Mifeprex as part of miscarriage management, as has become the standard of care. The Form does not describe the clinical circumstances of patients

experiencing pregnancy loss, and can be confusing and distressing for them. Nevertheless, because of the REMS, I still must have these patients sign the Form before I can prescribe them Mifeprex. For all of these reasons, the Patient Agreement Form interferes with my ability to practice my profession in accordance with my medical judgment.

25. I hope that more clinicians within our health care system will begin providing Mifeprex at their own hospitals and clinics as well, and thus continue to expand access to this safe and effective medication. I have had numerous conversations with like-minded colleagues to that end, including giving them advice about navigating the multi-step, time-consuming process I described above to register with both our health care system and with Danco as a prescriber and then to actually get the medication onsite. Unfortunately, these logistical hurdles caused by the REMS have proven to be a significant deterrent, and there are still only a handful of us in the health care system who prescribe Mifeprex, either for abortion care or for miscarriage management.

I declare under penalty of perjury that the foregoing is true and correct.

Executed in [redacted], on [redacted], 2021.

[redacted]

[redacted], M.D., a/k/a Jane Roe, M.D.